What’s New
January 2018 CAMLAB Update 2
Effective as Noted

This “What’s New” section is intended to help get you up to speed regarding the substantive changes that have been made to the CAMLAB since its previous update. Major changes to requirements, accreditation policies and procedures, and other important information in this update include the following:

- Addition of “Patient Safety Systems” (PS) chapter to inform and educate laboratories about the importance and structure of integrated patient safety systems
- Completed Phase 4 of the Standards Review Project, resulting in the consolidation and movement of standards within the “Human Resources” (HR) and “Infection Prevention and Control” (IC) standards
- Additional revisions made to the “Environment of Care” (EC) chapter as part of the alignment with the 2012 Life Safety Code®

Introduction: How The Joint Commission Can Help You Move Toward High Reliability (INTRO)

Effective January 1, 2018

- About the Comprehensive Accreditation Manual for Laboratory and Point-Of-Care Testing:
  - Clarified the complimentary access to E-dition® and to The Joint Commission Connect™ extranet site and contents/purpose for each
  - Added new paragraph regarding e-Alerts access
  - Clarified access and availability details of Perspectives
  - Updated information detailing how standards changes are made
- Table 1. Acronyms Used in This Manual: Updated acronyms
- Accreditation Process Information: Added description for the new “Patient Safety Systems” (PS) chapter

*Life Safety Code®* is a registered trademark of the National Fire Protection Association, Quincy, MA.
Identifying Applicable Standards: Removed reference to the *Standards for Office-Based Surgery Practices*, which is no longer printed (content is available via E-dition only)

Assess Compliance with the Standards: Added references for more information on the Survey Analysis for Evaluating Risk™ (SAFER™) matrix

Stimulate Improvement:
- Updated guidance on standards compliance frequently asked questions
- Updated *Joint Commission Connect* resources and tools listing specific to laboratories

Keep Up With Changes to the Standards:
- Revised section title to “Keep Current With Standards Changes via *Perspectives*” to clarify that the most up-to-date information is published in *Perspectives*
- Added bullet about e-Alerts subscriptions for new content and updates

Standards Questions: Updated guidance for submitting questions

Minor editorial revisions

**Patient Safety Systems (PS)**

*Effective January 1, 2018*

- New chapter

**Accreditation Requirements**

**Accreditation Participation Requirements (APR)**

- No changes

**Document and Process Control (DC)**

- No changes

**Environment of Care (EC)**

*Effective January 1, 2018*

- EC.01.01.01, EPs 3–8: Renumbered as EPs 4–9, respectively
- EC.02.03.01, new EP 13: Added EP requiring laboratories to meet all other Health Care Facilities Code fire protection requirements, as related to NFPA 99-2012: Chapter 15
- EC.02.04.03, EPs 8–13 and 16: Renumbered as EPs 9, 11–15, and 17 respectively
EC.02.04.03, new EP 27: Added EP requiring laboratories to meet all other Health Care Facilities Code requirements for electrical equipment in a patient’s vicinity as related to NFPA 99-2012: Chapter 10

EC.02.05.01, EPs 2–4 and 6–11: Renumbered as EPs 3–5 and 7–12, respectively

EC.02.05.03, EP 1: Renumbered as EP 2 and clarified that laboratories provide emergency power within ten seconds for alarm systems as required by the Life Safety Code; updated NFPA references

EC.02.05.03, new EP 1: Added EP regarding Type 1 or Type 3 essential electrical systems

EC.02.05.03, EP 2: Renumbered as EP 3 and added Note to provide NFPA reference for guidance in establishing a reliable emergency power system

EC.02.05.03, EP 3: Renumbered as EP 5 and added Note to provide NFPA reference for guidance in establishing a reliable emergency power system

EC.02.05.03, EPs 7–9: Renumbered as EPs 8–10, respectively

EC.02.05.05, new EP 8: Added EP requiring laboratories to meet all other Health Care Facilities Code requirements for electrical systems and heating, ventilation, and air conditioning (HVAC) as related to NFPA 99-2012: Chapters 6 and 9

EC.02.05.07, EP 1: Clarified that laboratories will perform a monthly functional test of emergency lighting systems, exit signs, and task lighting for a minimum of 30 seconds and added NFPA reference

EC.02.05.07, EP 2: Revised to require laboratories to perform a functional test of battery-powered lights and exit signs for a duration of 1 ½ hours every 12 months and added NFPA reference

EC.02.05.07, EP 4: Renumbered as EP 5 and clarified that laboratories will test emergency generators beginning with a cold start and added NFPA reference

EC.02.05.07, new EP 4: Added EP requiring laboratories to inspect emergency power supply systems and components at least weekly and document results and completion dates; applied a © icon

EC.02.05.07, EP 5: Renumbered as EP 6 and deleted requirement regarding testing supplemental loads of 25% for 30 minutes and added NFPA reference

EC.02.05.07, EP 6: Renumbered as EP 7, clarified that laboratories test all automatic and transfer switches on the inventory and document test results and completion dates, and added NFPA reference
Emergency Management (EM)

- No changes

Human Resources (HR)

*Effective January 1, 2018*

- Standard HR.01.01.01: Deleted Introduction and revised standard to require the laboratory to verify staff qualifications
- HR.01.01.01, EP 1: Renumbered as HR.01.02.05, EP 1, revised Note to allow the individual to be available by electronic consultation and added footnote with a CLIA ’88 reference
- Standard HR.01.02.05: Added new Introduction (formerly under HR.01.01.01) regarding personnel positions for nonwaived testing according to CLIA ’88 and a CDC reference for full description
- HR.01.02.05, EPs 1 and 2: Combined and renumbered as HR.01.01.01, EP 2
- HR.01.02.05, EP 3: Renumbered as HR.01.01.01, EP 3, and added Note with CLIA ’88 reference
- HR.01.02.05, EP 6: Renumbered as HR.01.01.01, EP 6
- HR.01.02.07, EP 2: Deleted cross-reference to HR.01.02.05, EPs 1 and 2
- HR.01.04.01, EPs 1 and 2: Combined and numbered as EP 1
- HR.01.04.01, EPs 3–6: Combined and numbered as EP 3
- HR.01.04.01, EPs 10 and 12: Combined and numbered as EP 10
- HR.01.05.03, EPs 1 and 4: Combined and numbered as EP 1
- HR.01.06.01, EP 21: Deleted cross-reference to HR.01.05.03, EP 4
- Minor editorial revisions

Infection Prevention and Control (IC)

*Effective January 1, 2018*
IC.01.03.01, EPs 2 and 5: Renumbered as EPs 1 and 3, respectively
IC.01.04.01, EPs 1–5: Combined and numbered as EP 1
IC.01.05.01, EP 6: Deleted cross-reference to HR.01.04.01, EPs 2 and 4
IC.02.01.01, EP 7: Deleted cross-reference to HR.01.04.01, EP 4
IC.02.03.01, EPs 2 and 3: Combined and numbered as EP 2
IC.02.04.01, EP 2: Deleted cross-reference to HR.01.04.01, EP 4
IC.02.04.01, EP 6: Deleted cross-reference to IC.02.04.01, EP 1
IC.03.01.01, EPs 1–4: Combined and numbered as EP 1
Minor editorial revisions

Information Management (IM)
- No changes

Leadership (LD)
- No changes

National Patient Safety Goals (NPSG)

*Effective January 1, 2018*
- NPSG.07.01.01, EP 1: Changed cross-reference from IC.01.04.01, EP 5 to EP 1
- NPSG.07.01.01, EP 2: Changed cross-reference from IC.03.01.01, EP 3 to EP 1

Performance Improvement (PI)
- No changes

Quality System Assessment for Nonwaived Testing (QSA)

*Effective January 1, 2018*
- QSA.02.12.01, EPs 4–8: Deleted cross-reference to QSA.02.04.01, EP 8

Transplant Safety (TS)
- No changes

Waived Testing (WT)
- No changes

Accreditation Process Information
The Accreditation Process (ACC)

Currently effective
- Tailored Survey Policy: Added footnote clarifying that contractual arrangements are evaluated for tailoring applicability on a case-by-case basis
- Complex Organization Survey Process: Noted that the electronic application for accreditation (E-App) specifies the manual(s) under which particular services are surveyed
- Concurrent Survey Option: Clarified that each participating laboratory under a separate health care organization identification number receives a separate survey report and accreditation decision
- Data Release to Government Agencies and Organizations with Which The Joint Commission Performs Coordinated Survey Activities: Removed the restriction that complaint information can be shared only if allegation(s) result in an on-site visit
- Role of the Account Executive: Updated to reflect that an account executive is assigned to an applicant organization after The Joint Commission receives a nonrefundable deposit (in addition to the E-App)
- Electronic Application for Accreditation (E-App): Added phone number organizations should contact for initial access to Joint Commission Connect
- Forfeiture of Survey Deposit: Added footnote clarifying circumstances in which accredited organizations are not charged a deposit
- During the Survey: Updated to reflect that “off-shift” survey activities could occur during early morning (as well as evening, night, and weekend) hours as necessary
- Survey Agenda: Added language to reflect that surveyors will discuss the Survey Analysis for Evaluating Risk™ (SAFER™) reporting process during the opening and exit conferences as well as during daily briefings
- Risk Areas: Added language about how surveyors will assess and display the risk associated with findings by utilizing the SAFER Matrix
- How Accreditation Decisions Are Made: Changed wording from “insufficiently compliant” to “noncompliant” in regard to EPs that will be cited as Requirements for Improvement (RFIs)
- Figure 5. SAFER Matrix placement and required follow-up activities: Revised language to align with updated Evidence of Standards Compliance (ESC) format
Corrective ESC: Updated to include the components of leadership involvement and preventive analysis
- Made minor editorial revisions

Effective January 1, 2018
- Decision Rules for Organizations Seeking Initial Accreditation: Made the following changes:
  - Added introductory text regarding the approval of decision rules by executive leadership (language applies to organizations seeking reaccreditation as well)
  - In Denial of Accreditation (DA) decision rule DA07, replaced the bulleted list of how a laboratory provides information to The Joint Commission with the words “in any way”
  - Added new rule DA10 regarding individuals who do not possess or are practicing outside the scope of a license, registration, or certification
  - Added new rule DA11 regarding organizations that do not possess a license, certificate, and/or permit

- Decision Rules for Organizations Seeking Reaccreditation: Made the following changes:
  - Deleted Evidence of Standards Compliance (ESC) decision rule ESC03 regarding on-site evaluations to validate compliance with the relevant standards in a written ESC
  - Deleted Accreditation with Follow-up Survey (AFS) decision rule AFS04 (which involved at least two on-site ESC demonstrating the need for continued monitoring)
  - Deleted cross-reference to LD.04.02.03, EP 3 from AFS12 to align with LD chapter
  - Added new rule AFS13 regarding laboratories that implement sufficient corrective action as demonstrated in an on-site validation survey (related to Preliminary Denial of Accreditation [PDA] rule PDA02)
  - In PDA05, replaced the bulleted list of how a laboratory provides information to The Joint Commission with the words “in any way”
  - Deleted cross-reference to LD.04.02.03, EP 3 from PDA10 to align with LD chapter
Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing

- Added new rule PDA11 on what happens when the Immediate Threat to Health or Safety abatement survey has not demonstrated implementation of sufficient corrective action
- Added new rule DA06 regarding organizations that receive a Preliminary Denial of Accreditation (PDA) decision in two sequential surveys

Standards Applicability Grid (SAG)

Effective January 1, 2018
- Added applicability for the following new EPs:
  - EC.02.03.01, new EP 13
  - EC.02.04.03, new EP 27
  - EC.02.05.03, new EP 1
  - EC.02.05.05, new EP 8
  - EC.02.05.07, new EP 4
- Revised service applicability for the following EPs:
  - EC.01.01.01, EPs 1 and 4–9
  - EC.02.03.01, EPs 1, 3, 4, 9, and 10
  - EC.02.04.03, EPs 4, 6, 7, 9, 11–13, and 17
  - EC.02.05.01, EPs 3–5, and 7–13
  - EC.02.05.03, EPs 2, 3, 5, and 8–10
  - EC.02.05.05, EPs 1 and 5
  - EC.02.05.07, EPs 1–3, 5–7, 9, and 10
- Made the changes to align with standards consolidations and movements throughout the manual

Sentinel Events (SE)

Effective January 1, 2018
- Definition of Sentinel Event: Updated link in “severe, temporary harm” footnote
- Minor editorial revisions

The Joint Commission Quality Report (QR)

Effective January 1, 2018
- What Is the Joint Commission Quality Report?: Clarified the type of information available on the Quality Report website
What Will My Quality Report Contain?: Removed reference to Quality Indicators that compare organizations on a state and national level

How Does My Hospital Submit a Commentary?: Clarified the approval process necessary for submitting a commentary to accompany your Quality Report

Updated or added web addresses throughout the chapter

Minor editorial revisions

Required Written Documentation (RWD)

Effective January 1, 2018

Added documentation requirement to EC.02.05.07, new EP 4

Made the following changes to align with standards changes throughout the manual:

- EC.01.01.01, EPs 3–8: Renumbered as EPs 4–9
- EC.02.04.03, EPs 8–11, and 16: Renumbered as EPs 9, 11–13, and 17
- EC.02.05.01, EPs 2–4, 7, and 9: Renumbered as EPs 3–5, 8, and 10
- EC.02.05.07, EPs 4, 6, and 7: Renumbered as EPs 5, 7, and 9
- HR.01.02.05, EPs 1 and 2: Combined and renumbered as HR.01.01.01, EP 2
- HR.01.02.05, EP 3: Renumbered as HR.01.01.01, EP 3
- HR.01.04.01, EP 2: Renumbered as EP 1
- HR.01.04.01, EPs 3–6: Combined and numbered as EP 3
- HR.01.04.01, EPs 10 and 12: Combined and numbered as EP 10
- HR.01.05.03, EPs 1 and 4: Combined and numbered as EP 1
- IC.01.03.01, EP 5: Renumbered as EP 3
- IC.01.04.01, EPs 1–5: Combined and numbered as EP 1

Early Survey Policy (ESP)

Effective January 1, 2018

Added the following EPs applicable to a first survey under the Early Survey Policy Option:

- EC.02.03.01, new EP 13
- EC.02.04.03, new EP 27
- EC.02.05.03, new EP 1
- EC.02.05.05, new EP 8
- EC.02.05.07, new EP 4
Made the following changes to align with standards changes throughout the manual:

- EC.01.01.01, EPs 3–8: Renumbered as EPs 4–9
- EC.02.04.03, EPs 8–12 and 16: Renumbered as EPs 9, 11–14, and 17
- EC.02.05.01, EPs 2–4 and 6–11: Renumbered as EPs 3–5 and 7–12
- EC.02.05.03, EPs 1–3 and 7–9: Renumbered as EPs 2, 3, 5, and 8–10
- EC.02.05.07, EP 5: Renumbered as EP 6
- HR.01.02.05, EPs 1 and 2: Combined and renumbered as HR.01.01.01, EP 2
- HR.01.02.05, EPs 3 and 6: Renumbered as HR.01.01.01, EPs 3 and 6
- HR.01.04.01, EPs 1 and 2: Combined and numbered as EP 1
- HR.01.04.01, EPs 3–6: Combined and numbered as EP 3
- HR.01.04.01, EPs 10 and 12: Combined and numbered as EP 10
- HR.01.05.03, EPs 1 and 4: Combined and numbered as EP 1
- IC.01.03.01, EPs 2 and 5: Renumbered as EPs 1 and 3
- IC.01.04.01, EPs 1–5: Combined and numbered as EP 1
- IC.02.03.01, EPs 2 and 3: Combined and numbered as EP 2
- IC.03.01.01, EPs 1–4: Combined and numbered as EP 1

Appendix A: Retention Times for Records, Reports, and Specimens (AXA)
- No changes

Appendix B: Laboratory Developed Tests (AXB)
- No changes

Appendix C: Individualized Quality Control Plan–Eligible Requirements (AXC)
- No changes

Glossary

Effective January 1, 2018

- Deleted the term *environmental tours*
- Minor editorial revisions
The Joint Commission Mission
The mission of The Joint Commission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

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Introduction: How The Joint Commission Can Help You Move Toward High Reliability (INTRO)

The “Introduction: How The Joint Commission Can Help You Move Toward High Reliability” (INTRO) chapter is an introduction to Joint Commission accreditation and a user’s guide to understanding how the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB) and its E-dition® are organized. There are four parts to guide you toward compliance and support your journey to high reliability:

1. Part I provides a brief overview of the value of Joint Commission accreditation and the Laboratory Accreditation Program.
2. Part II explains the organization and content of the CAMLAB.
3. Part III explains how you can use the CAMLAB to successfully achieve and maintain compliance with Joint Commission standards. Part III also provides tips and strategies for finding the information you need to stay current with Joint Commission standards and understand the on-site survey process.
4. Part IV provides a comprehensive list of contacts and resources you can use to get more information at The Joint Commission and Joint Commission Resources.

Read this chapter first to understand the Laboratory Accreditation Program and the structure and content of the CAMLAB. After you have a better understanding of the value of accreditation in improving and maintaining the quality of care, treatment, or services, maximizing patient safety, and stimulating performance improvement, read “The Accreditation Process” (ACC) chapter to understand the Joint Commission’s accreditation process, including eligibility for accreditation; the application process; accreditation surveys and what to expect before, during, after, and between surveys; accreditation decision rules; and review and appeal procedures.

I. Introduction to Joint Commission Accreditation
The Value of Joint Commission Accreditation

The Joint Commission’s Gold Seal of Approval® is a widely recognized benchmark representing the most comprehensive evaluation process in the health care industry. Joint Commission accreditation benefits your organization in the following ways:

- **Gives you a competitive advantage:** Achieving accreditation is a visible demonstration to patients and the community that your laboratory is committed to providing the highest-quality services. It also sets you apart from other laboratories offering the same types of care, treatment, or services.

- **Assists with recognition from insurers, associations, and other third parties:** Some payers, state regulatory agencies, government agencies, and managed care contractors require Joint Commission accreditation for reimbursement, for certification or licensure, and as a key element of their participation agreements and reimbursement practices.

- **Helps organize and strengthen your improvement efforts:** Accreditation encompasses state-of-the-art performance improvement concepts that help you continuously improve quality and standardize your processes of care, treatment, or services.

- **Helps health care organizations become high reliability organizations:** The Joint Commission offers numerous resources and information to help laboratories move toward high reliability—that is, to consistently perform at high levels of quality and safety across all services and to maintain these levels over long periods. These resources help leadership commit to high reliability by making it a priority, establishing a safety culture throughout the organization that emphasizes trust and the reporting of unsafe conditions and improvement, and encouraging laboratories to use Robust Process Improvement® (RPI®) tools and methodologies (such as Lean, Six Sigma, and change management) to systematically improve processes and avoid common, crucial failures.

- **Enhances staff education:** The accreditation process is designed to be educational. Joint Commission surveyors share best practice approaches and strategies that may help your laboratory better meet the intent of the standards and, more important, improve performance of day-to-day operations.

- **Provides access to experts in quality and safety:** The Joint Commission is committed to helping your laboratory move toward high reliability in your organization. Through The Joint Commission, your laboratory has access to a range of professionals eager to see you succeed. It starts with the assignment of an account executive specializing in laboratories to help in day-to-day accreditation activities. You also have ready access to the clinical or engineering experts in our Standards Interpretation Group.
(SIG) as well as professional surveyors who visit your organization for on-site surveys and clinicians who are available to help provide expert analysis of sentinel events in the Office of Quality and Patient Safety.

Figure 1 illustrates how Joint Commission accreditation guides laboratories in achieving, maintaining, and demonstrating consistent excellence in quality and safety. Part III of this chapter (Steps to Achieving and Maintaining Compliance) provides additional detail on other tools and resources available to accredited organizations.

**Figure 1.** The Joint Commission’s Laboratory Accreditation Program is designed to help laboratories achieve, maintain, and demonstrate consistent excellence in the services they provide to patients. The program has several key components designed to work collectively to better power your overall performance improvement efforts.
The Joint Commission’s Laboratory Accreditation Program
The Joint Commission’s Laboratory Accreditation Program uses a patient-centered quality framework and collaborative approach to help organizations proactively identify and address vulnerabilities to safeguard patients.

Addressing Complex Issues in Laboratories Accredited by The Joint Commission
There are many factors that affect the outcomes patients receiving laboratory services experience. For example, a sufficient number of staff members to support testing services will help prevent adverse outcomes such as inaccurate or delayed testing results. Likewise, having educated, competent, and properly trained staff positively impacts the organization’s ability to assess, plan, and deliver safe, high-quality test results in a timely manner.

Research shows that some of the greatest challenges for laboratories are addressing diagnostic errors, obtaining optimum patient specimens that are labeled correctly, order entry mistakes, equipment performance, clerical errors, and failures in the reporting of test results and other required documentation. In addition, staff and leadership are challenged with abandoning institution-centered practices and embracing patient-centered approaches in the laboratory.

The Laboratory Accreditation Program helps providers achieve, maintain, and demonstrate consistent excellence in the services they provide. The standards specifically listed in Table 1 can help laboratories develop strategies to address some of the most challenging and complex patient issues described previously.

Note: Table 1 does not address all of the issues facing leaders in laboratories.
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Table 1. Standards That Address Complex Issues in Laboratories

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Focusing on the patient and following the direction provided in the standards in Table 1 will allow staff to begin to explore ways to improve services that help patients in attaining the most favorable outcomes possible. The Intracycle Monitoring (ICM) process (discussed in more detail in “The Accreditation Process” [ACC] chapter) and the information on your Joint Commission Connect® extranet site, in combination with a focus on the complex issues addressed by these standards, will help you assess just how ready for accreditation your organization is and will allow you to continually assess your organization’s readiness going forward.
II. About the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing

The CAMLAB (and its web-based, fully searchable, electronic version called the E-dition) contains Joint Commission standards (also known as requirements), elements of performance (EPs), National Patient Safety Goals® (NPSGs), and other requirements applicable to the care, treatment, or services a laboratory provides (see the “Identifying Applicable Standards” section in this chapter). The CAMLAB includes all the information a laboratory needs to achieve and maintain continuous compliance with the Joint Commission’s accreditation and optional specialty certification standards. The manual also will help laboratories engage in continuous performance improvement and will guide staff in developing processes to provide the highest quality of safe care, treatment, and services.

Upon initial application for accreditation and, if required, receipt of a deposit toward accreditation fees, a laboratory receives complimentary access to E-dition (which contains accreditation standards) and access to the Joint Commission Connect extranet (which contains various accreditation tools and resources). This secure extranet site also serves as the primary avenue for communication between an organization and The Joint Commission.

The Joint Commission may revise accreditation or certification standards periodically throughout the year and publish those changes online, in the accreditation manual, or in Joint Commission Perspectives®. This official Joint Commission newsletter publishes revised or updated standards, EPs, scoring, standards clarifications and interpretations, and other useful information as the year progresses. Your organization is responsible for meeting all applicable standards published in Perspectives, and staff need access to aid in your compliance efforts (see “Keep Current With Standards Changes via Perspectives” section). (Perspectives is available on your Joint Commission Connect extranet site, under the “Resources” tab or is available for purchase at www.jcrinc.com/the-joint-commission-perspectives/.) Modifications and clarifications to Joint Commission standards published in Perspectives can also be found online at https://www.jointcommission.org/standards_information/tjc_requirements.aspx.
The Joint Commission website offers e-Alerts for new content or updates. For more information, visit https://www.jointcommission.org/ealerts/. Sign up for or update e-Alerts subscriptions at http://www.jointcommission.org/thickbox/NewsletterSign-Up.aspx.

Changes to the standards can be made for a variety of reasons, but they are always done with input from accredited organizations, health care professionals, providers, subject matter experts, consumers, government agencies, and/or employers and are informed by the scientific literature. New standards are added only if they relate to patient safety or quality of care and/or have a positive impact on health outcomes, can be accurately and readily measured, and relate to important issues that clearly support high-quality care, treatment, and services. Standards may also be revised in response to law and regulation changes.

Although The Joint Commission may announce revisions to accreditation standards throughout the year, those changes are made to the E-dition generally only twice a year: in the spring (with changes applicable July 1) and in the fall (with changes applicable January 1 of the following year). Accredited organizations receive one complimentary subscription to the E-dition as long as they maintain accreditation. The print version of the CAMLAB manual is published once a year in the fall; it is only available for purchase at http://www.jcrinc.com/store/publications/manuals/. The “What’s New” table, provided with each print manual and accessible from the blue navigation bar across the top of the E-dition, offers a summary of the changes made since the CAMLAB was last published or posted.

How Is This Manual Organized?
This manual is organized into the following two sections for your convenience:

- **Section 1: Accreditation Requirements** (marked with gold tabs in the print version). These chapters include standards that are scored, and they appear in alphabetical order.
- **Section 2: Accreditation Process Information** (marked with blue tabs in the print version). This section includes information about the accreditation process, policies, procedures, and other related information.

Following is more detail about each section. See Table 2 for a list of acronyms used in this manual.
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACC</td>
<td>“The Accreditation Process” chapter</td>
</tr>
<tr>
<td>AFS</td>
<td>Accreditation with Follow-up Survey</td>
</tr>
<tr>
<td>APR</td>
<td>“Accreditation Participation Requirements” chapter</td>
</tr>
<tr>
<td>CAMLAB</td>
<td><em>Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing</em></td>
</tr>
<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments</td>
</tr>
<tr>
<td>CMS</td>
<td>US Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>DA</td>
<td>Denial of Accreditation</td>
</tr>
<tr>
<td>DC</td>
<td>“Document and Process Control” chapter</td>
</tr>
<tr>
<td>E-App</td>
<td>electronic application for accreditation</td>
</tr>
<tr>
<td>EC</td>
<td>“Environment of Care” chapter</td>
</tr>
<tr>
<td>EM</td>
<td>“Emergency Management” chapter</td>
</tr>
<tr>
<td>EP</td>
<td>element of performance</td>
</tr>
<tr>
<td>ESC</td>
<td>Evidence of Standards Compliance</td>
</tr>
<tr>
<td>ESP</td>
<td>Early Survey Policy (option for organizations not previously accredited)</td>
</tr>
<tr>
<td>FOC</td>
<td>Focused Survey</td>
</tr>
<tr>
<td>FSA</td>
<td>Focused Standards Assessment</td>
</tr>
<tr>
<td>HAI</td>
<td>health care–associated infection</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act of 1996</td>
</tr>
<tr>
<td>HR</td>
<td>“Human Resources” chapter</td>
</tr>
<tr>
<td>IC</td>
<td>“Infection Prevention and Control” chapter</td>
</tr>
<tr>
<td>ICM</td>
<td>Intracycle Monitoring</td>
</tr>
<tr>
<td>ILSM</td>
<td>interim life safety measures</td>
</tr>
<tr>
<td>IM</td>
<td>“Information Management” chapter</td>
</tr>
</tbody>
</table>

*continued on next page*
### Table 2. *(continued)*

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRO</td>
<td>“Introduction: How The Joint Commission Can Help You Move Toward High Reliability” chapter</td>
</tr>
<tr>
<td>IQCP</td>
<td>Individualized Quality Control Plan (a voluntary quality control option for clinical laboratories)</td>
</tr>
<tr>
<td>LD</td>
<td>“Leadership” chapter</td>
</tr>
<tr>
<td>LTA</td>
<td>Limited, Temporary Accreditation</td>
</tr>
<tr>
<td>NPSG</td>
<td>National Patient Safety Goal (also a chapter in this manual)</td>
</tr>
<tr>
<td>OQPS</td>
<td>Office of Quality and Patient Safety</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>PDA</td>
<td>Preliminary Denial of Accreditation</td>
</tr>
<tr>
<td>PFI</td>
<td>Plan for Improvement</td>
</tr>
<tr>
<td>PI</td>
<td>“Performance Improvement” chapter</td>
</tr>
<tr>
<td>POA</td>
<td>Plan of Action</td>
</tr>
<tr>
<td>PS</td>
<td>“Patient Safety Systems” chapter</td>
</tr>
<tr>
<td>QR</td>
<td>“The Joint Commission Quality Report” chapter</td>
</tr>
<tr>
<td>QSA</td>
<td>“Quality System Assessment for Nonwaived Testing” chapter</td>
</tr>
<tr>
<td>RCA</td>
<td>root cause analysis</td>
</tr>
<tr>
<td>RFI</td>
<td>Requirement for Improvement</td>
</tr>
<tr>
<td>RWD</td>
<td>“Required Written Documentation” chapter</td>
</tr>
<tr>
<td>SAFER™</td>
<td>Survey Analysis for Evaluating Risk™</td>
</tr>
<tr>
<td>SAG</td>
<td>“Standards Applicability Grid” chapter</td>
</tr>
<tr>
<td>SE</td>
<td>“Sentinel Events” chapter</td>
</tr>
<tr>
<td>SIG</td>
<td>Standards Interpretation Group</td>
</tr>
<tr>
<td>SOC™</td>
<td>Statement of Conditions™</td>
</tr>
<tr>
<td>TS</td>
<td>“Transplant Safety” chapter</td>
</tr>
<tr>
<td>WT</td>
<td>“Waived Testing” chapter</td>
</tr>
</tbody>
</table>
Accreditation Requirements
The first section of this manual contains the accreditation standards for the Laboratory Accreditation Program, which consists of Joint Commission standards, EPs, NPSGs, and other requirements applicable to all organizations accredited in the Laboratory Accreditation Program.

This manual contains the following standards chapters:

“Accreditation Participation Requirements” (APR): Consists of specific requirements for participation in the accreditation process and for maintaining an accreditation award.

“Document and Process Control” (DC): Contains a comprehensive set of requirements for the pre- and post-analytical phases of testing and describes the procedures for specimen collection, ordering of laboratory tests, and step-by-step description of the performance of each test.

“Environment of Care®” (EC): Describes how to maintain a safe, functional, and effective environment for patients, staff, and other individuals in the organization.

“Emergency Management” (EM): Ensures that the organization has a disaster plan in place.

“Human Resources” (HR): Outlines requirements for personnel roles required for nonwaived testing as listed in the Clinical Laboratory Improvement Amendments of 1988 and processes for staff orientation, training, competency, and management.

“Infection Prevention and Control” (IC): Helps organizations identify and reduce the risk of acquiring and transmitting infections.

“Information Management” (IM): Directs organizations to obtain, manage, and use information to provide, coordinate, and integrate care, treatment, and services.

“Leadership” (LD): Reviews structure and relationships of leadership and the maintenance of a culture of safety, quality, and operational performance.

“National Patient Safety Goals” (NPSG): Includes specific actions that organizations are expected to take to prevent medical errors, such as harm associated with inaccurate patient identification, delayed communication on critical test results, and health care–associated infections.
“Performance Improvement” (PI): Focuses on using data to monitor performance, compiling and analyzing data to identify improvement opportunities, and taking action on improvement priorities.

“Quality System Assessment for Nonwaived Testing” (QSA): Focuses on specific analytical requirements to produce quality nonwaived test results. Also includes regulatory requirements on proficiency testing and quality control requirements.

“Transplant Safety” (TS): Focuses on the development and implementation of policies and procedures for safely acquiring, receiving, storing, and issuing tissues.

“Waived Testing” (WT): Covers policies, identifying staff responsible for performing and supervising waived testing, competency requirements, quality control, and record keeping.

Accreditation Process Information
The second section of this manual contains information about the accreditation process, policies, procedures, and other related information. The following chapters appear in this section:

“Patient Safety Systems” (PS): Informs and educates leadership about the importance and structure of an integrated patient safety system. This chapter is designed to clarify the relationship between Joint Commission accreditation and patient safety. It does not contain new standards or requirements. Rather, the chapter describes how existing requirements can be applied to continually improve patient safety. It also provides approaches and methods that may be adapted to remove risk of patient harm.

“The Accreditation Process” (ACC): Provides information about the Joint Commission’s accreditation process, including the application process, types of surveys, Tailored Survey Policy, Intracycle Monitoring (ICM), and Focused Standards Assessment (FSA). The chapter also describes all components of the accreditation process, including the survey agenda, tracer methodology, the Joint Commission’s Information Accuracy and Truthfulness Policy, and the Public Information Policy. Details of the scoring and decision process, including the Accreditation Decision Rules, Evidence of Standards Compliance, and the review and appeal process, are also explained.
“Standards Applicability Grid” (SAG): Provides a list of the standards that are applicable to laboratories. The user-friendly format allows you to quickly identify the services, as you identified them in your E-App, and the related standards that apply to your laboratory.

“Sentinel Events” (SE): Contains information on the Joint Commission’s Sentinel Event Policy, including the definition of a sentinel event, the goals of the policy, the adverse events that constitute sentinel events, sentinel event–related standards, and the various activities that surround the policy.

“The Joint Commission Quality Report” (QR): Provides an overview of publicly viewable accreditation information provided in the form of Quality Reports. It describes what Quality Reports are, how and when they are developed, how organizations can respond to them, and how the public and organizations can access and use them. It also includes information about the Joint Commission’s Quality Check® website, guidelines for submitting commentary, and marketing and communicating guidelines for using Quality Reports.

“Required Written Documentation” (RWD): Lists the standards that require written documentation beyond that required in the medical record—that is, all the EPs marked with a icon throughout the standards chapters. This chapter can be used as a checklist by accredited organizations to maintain continuous compliance with documentation requirements or by organizations seeking accreditation to verify compliance with those requirements.

“Early Survey Policy” (ESP): Lists the selected standards, EPs, and other requirements that are surveyed during the first survey when a laboratory has chosen the Early Survey Policy option. This chapter can be referenced as you prepare for first-time accreditation under the ESP. See “The Accreditation Process” (ACC) chapter for details on the ESP.

“Appendix A: Retention Times for Records, Reports, and Specimens” (AXA): Lists the minimum required retention times for various records, reports, and specimens. In instances where state or local regulations require longer retention periods, the laboratory must conform to those.

“Appendix B: Laboratory Developed Tests” (AXB): Lists the standards and EPs that, in addition to those found in the Molecular Biology column of the SAG chapter, may be applicable to laboratories performing Laboratory Developed Tests (LDTs) in a particular specialty or subspecialty.
“Appendix C: Individualized Quality Control Plan–Eligible Requirements” (AXC):
Contains the general and specialty/subspecialty quality control requirements eligible for the Individualized Quality Control Plan (IQCP) approach. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP-eligible Joint Commission quality control requirements.

“Glossary” (GL): Provides definitions of many terms used throughout the manual.

“Index” (IX): Appears at the end of the print manual.

Identifying Applicable Standards
The print version of the CAMLAB includes all Joint Commission standards that apply to all organizations accredited under the Laboratory Accreditation Program. But not all standards in the print manual apply to the specific care, treatment, or services that your individual organization provides; your settings; or the populations you serve. You are not expected to comply with standards that do not apply to the services, settings, or populations of your organization. If you are unsure about the standards in the print manual that apply to your laboratory, please review the SAG chapter.

In contrast, the E-dition on your Joint Commission Connect extranet site displays only the standards applicable to your organization as identified in your E-App. The E-App gives your organization the ability to select the specific laboratory settings that describe your organization and the specific services you provide. This selection, in turn, drives the standards applied to your organization by surveyors during the on-site survey process. To view your organization’s services in E-dition, click “Service Profile” on the top navigation bar. Check with your Joint Commission account executive if you have questions or to help you ensure your E-App is complete and accurate.

Some organizations provide care, treatment, or services that are covered under more than one accreditation program and manual (for example, a laboratory with an ambulatory care center/clinic or home care setting will be required to maintain compliance with certain standards in the ambulatory or home care accreditation manuals as well as the CAMLAB). The Joint Commission will work with your organization to determine whether standards from this and/or other accreditation manuals are applicable.
The Joint Commission surveys and accredits health care organizations using standards from one or more of eight accreditation programs (the names of the corresponding print manuals are indicated in parentheses):

1. **Ambulatory Care (Comprehensive Accreditation Manual for Ambulatory Care):**
   Surgery centers, community health centers, group practices, imaging centers, sleep labs, rehabilitation centers, telehealth providers, student health centers, urgent care clinics, and other ambulatory providers

2. **Behavioral Health Care (Comprehensive Accreditation Manual for Behavioral Health Care):** Organizations that provide mental health services, substance use treatment services, foster care services, programs or services for children and youth, child welfare, services for individuals with eating disorders, services for individuals with intellectual/developmental disabilities of various ages and in various organized service or program settings, case management services, peer-based recovery services, prevention and wellness promotion services, corrections-based services, and opioid treatment programs

3. **Critical Access Hospital (Comprehensive Accreditation Manual for Critical Access Hospitals):** A hospital that offers limited services and is located more than 35 miles from a hospital or another critical access hospital, or is certified by the state as being a necessary provider of health care services to residents in the area. It maintains no more than 25 beds that could be used for inpatient/swing bed care. A critical access hospital provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient. A critical access hospital can also have a psychiatric and/or rehabilitation distinct part unit; each unit can have up to 10 beds.

4. **Home Care (Comprehensive Accreditation Manual for Home Care):** Organizations that provide home health services, personal care and support services, pharmacy services including infusion services and/or mail order and specialty pharmacies, long term care pharmacies and freestanding infusion centers, durable medical equipment services, and hospice services

5. **Hospital (Comprehensive Accreditation Manual for Hospitals):** General, acute psychiatric, pediatric, medical/surgical specialty, long term acute care, and rehabilitation hospitals

6. **Laboratory Services (Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing):** Clinical laboratories, point-of-care testing, assisted reproductive technology labs, and reference labs performing nonwaived testing
7. Nursing Care Centers (Comprehensive Accreditation Manual for Nursing Care Centers): Organizations that provide specialized services to patients or residents, which may include rehabilitative care, dementia-specific memory care, and long-term nursing care.

8. Office-Based Surgery Practices: A surgeon-owned or -operated organization (for example, a professional services corporation, private physician office, or small group practice) that provides invasive procedures and administers local anesthesia, minimal sedation, conscious sedation, or general anesthesia that renders three or fewer patients incapable of self-preservation at any time, and is classified as a business occupancy.

Contact your account executive with questions about eligibility or the services or settings that will be included in your survey.

Understanding the Organization of the Standards Chapters
Each standards chapter in the “Accreditation Requirements” section is organized as follows (see Figure 2):

- **Overview:** The overview is located at the beginning of each chapter. The overview explains the chapter’s purpose and the principles on which the standards were built.
- **Chapter outline:** This part shows how the chapter is laid out and provides a frame of reference for the numbering of standards.
- **Introduction:** Some standards (or cluster of standards) have an introduction at the beginning, which provides information about the standard’s origin and any issues that surround it.
- **Standards:** Standards (also known as requirements) are statements that define the performance expectations and/or structures or processes that must be in place for organizations to provide safe, high-quality care, treatment, and services.
- **Rationale:** A rationale explains the purpose of a standard by providing additional background, justification, or other information, but it is not scored. In many cases, the rationale for a standard is self-evident; therefore, not every standard has a written rationale.
- **References:** This part of a chapter is placed in parentheses following a standard to help identify related standards, whether they are located in the same chapter or a different chapter. These references should help the user to quickly find related standards concerning a particular topic.
Elements of performance (EPs): EPs are statements that detail the specific performance expectations and/or structures or processes that must be in place for an organization to provide high-quality care, treatment, or services. EPs are scored and determine an organization’s overall compliance with a standard. The EPs are numbered sequentially under each standard: EP 1, EP 2, EP 3, and so on. Some EPs in standards common across accreditation programs may not apply specifically to laboratories and are omitted from this accreditation manual. Consequently, gaps may exist in the sequence. For example, if a standard lists EP 1, EP 2, and EP 5, this indicates that EP 3 and EP 4 do not apply to the Laboratory Accreditation Program and, therefore, your organization does not have to comply with them.

Notes: Notes are used to provide organizations and surveyors with additional or clarifying information about a specific EP.

Worksheets: The following worksheets are accessible on the chapter navigation bar in the E-dition and included at the end of each standards chapter in the print manual:

- Prompts to Assess Your Compliance: These worksheets contain questions to prompt discussion in your organization about compliance with the standards in a particular chapter. In some instances, there are tips with helpful standards compliance strategies.
- Written Documentation Checklist: These checklists contain the EPs that require written documentation (shown with a ☐ icon in the chapter) that a surveyor may ask to see during a survey to assess compliance.
- Action Planning Tool: These forms can be used to track EPs that are out of compliance and to document the steps your organization will take to bring them into compliance.
- Chapter Notes: These blank sheets in your print manual can be used to record notes and information, such as the location of documents or medical record numbers used to assess compliance, so you have them at the ready for reference.
Introduction: How The Joint Commission Can Help You Move Toward High Reliability

Figure 2. Components of a standards chapter in the print manual. The components are further described in the “Understanding the Icons Used in the Manual” section.

Understanding the Icons Used in the Manual
You will notice features in the manual that will help you navigate the standards. Icons used throughout the accreditation requirements chapters provide clarity and ease of use.

The following icons can be found in this manual:
The documentation icon indicates when written documentation is required to demonstrate compliance with an EP. In addition, the word *written* usually appears in the text if an EP requires written documentation, which may be in either a paper or an electronic format. Because The Joint Commission’s focus is on performance and implementation rather than documentation, the EPs require documentation only when it is essential. A documentation icon is used to identify data collection and documentation requirements that are beyond information required to be in the clinical record. For example, an EP that requires a written procedure will include a , but the icon is not applied to an EP that contains the required list of components of the clinical record. Other examples in which the documentation icon is used are for EPs that require a policy, a written plan, bylaws, a license, evidence of testing, data, performance improvement reports, medication labels, safety data sheets, or meeting minutes. Each EP that requires any of these types of documentation is listed in the Written Documentation Checklist at the end of each standards chapter in this manual.

The risk icon identifies specific risks by accreditation program (not program segment). Risk is assessed by a system’s proximity to the patient, probability of harm, severity of harm, and number of patients at risk. Risk categories identified by The Joint Commission are related to National Patient Safety Goals, accreditation program–specific risk areas, and RFIs identified during current accreditation cycle survey events. The print manual will show a single icon at the EP level for the National Patient Safety Goals and accreditation program–specific risk areas that are required to be addressed during the ICM process through the FSA. The third risk category—related to an organization’s own RFIs—will appear only in the ICM Profile on the organization’s *Joint Commission Connect* extranet site.

**III. Steps to Achieving and Maintaining Compliance**

Communicating critical information to staff and maintaining continuous compliance with Joint Commission standards are key to ensuring that safe, high-quality care is provided to patients—yet these charges present a real challenge for many organizations. Following are some helpful suggestions for successfully achieving continuous compliance with accreditation standards outlined in this accreditation manual.
**Become Familiar with the Standards**

Make the *CAMLAB* readily available to staff by keeping a copy or multiple copies of the print manual in an easily accessible location, such as a resource center or other central location. Let staff and others know that the manual is available and how they can access it.

Although there may be one or more staff members with sole accreditation responsibilities who should read all parts of each chapter in this manual, it is more likely that several individuals or teams will need to know and understand one or more sections or chapters. Therefore, it is important for organizations to make the information readily available to such staff.

The “Requesting Permission to Copy Content from the Manual” section provides contact information and guidelines for purchasing copies of the *CAMLAB*, requesting permission to make copies of your print manual, or purchasing a site license for the Edition to make accreditation standards more widely available to staff.

**Use the Standards to Improve Quality**

Laboratories face a number of complex issues and challenges when performing testing. Table 1 lists some of the most common and challenging issues in laboratories as well as the standards in the *CAMLAB* that help organizations address these topics. Laboratories should not view these standards—or any standards in the manual—as rules that must be followed just for Joint Commission survey purposes but should instead incorporate tasks and processes that help integrate these concepts into your daily operations because they directly affect the safety of patients and the quality of care, treatment, and services you provide.

**Assess Compliance with the Standards**

Determine whether your organization is in compliance and how consistently you are performing. This can be accomplished in a number of ways, including the following:

- Create or use a checklist to evaluate compliance for each standard, or turn each standard into a question. For example: Is our interdisciplinary team consulted when necessary to determine whether a prospective patient is eligible for admission? Does my organization assess the patient’s risk for falls?
Monitor the Joint Commission website for free tools and resources provided. For example, The Joint Commission published a crosswalk of Clinical and Laboratory Standards Institute documents referenced to Joint Commission standards at https://www.jointcommission.org/assets/1/18/CLSI_JC-Cross-Walk_Final_WebVersion.pdf.


Use the worksheets at the end of each standards chapter to track compliance with the standards in the chapter and to trace progress for coming into compliance.

Turn accreditation standards into PowerPoint presentations, handouts, study aids, posters, or other staff education materials. They also can be rewritten as quizzes, tests, or worksheets to determine staff understanding.

Use the ICM profile and FSA tool on your Joint Commission Connect extranet site to prepare for your initial survey or maintain compliance between surveys (see Figure 3). Contact your account executive for support.

Compile information on your performance improvement activity for discussion during your on-site survey.

Form a team to develop creative ways to assess, achieve, and maintain standards compliance, such as the following:
- Question of the week or month
- Standards-related posters
- Column in a weekly all-staff newsletter or electronic bulletin board

Speak to other accredited program coordinators. To find other accredited programs, go to http://www.qualitycheck.org and search by organization, service/setting, state, city, or zip code.

Conduct a gap analysis for the activities required by the standards and evaluate your organization against each standard. Identify whether the standard is being (or has been) met or not met.
KEY MILESTONES IN THE ACCREDITATION PROCESS

Joint Commission Activities

Full on-site survey is conducted using tracer methodology
Summary of findings left for organization
On-site survey is scheduled
Accreditation decision rendered
Quality Report™ posted on Quality Check®
FSA activated for submission (due by month 9)
On-site resurvey is scheduled
Full survey is conducted (between months 18 and 24)
Biennial accreditation cycle begins again

Accredited Organization Activities

-6 -3 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Year One Year Two

-6 Application
-3 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24

Activities: The Joint Commission completes appear above the timeline; activities conducted by the organization appear below the timeline.

FSA, Focused Standards Assessment; SIG, Standards Interpretation Group; POA, Plan of Action; E-App, electronic application; ICM, Intracycle Monitoring; ESC, Evidence of Standards Compliance.
Stimulate Improvement

After a standards assessment has been completed, there likely will be follow-up action needed to bring your organization into compliance. Following are tips to make sure your organization complies with Joint Commission standards and meets the needs of your patients for safe, high-quality care.

- Contact your Account Executive with questions about what standards apply to your organization or how to apply Accreditation Participation Requirements (see the “Account Executive” section for contact information).
- Educate key staff on how to access E-dition standards under the “Resources” section on your Joint Commission Connect extranet site. E-dition contains the most current standards in an electronic format.
- Create an online Joint Commission electronic bulletin board on your organization’s internal website to give staff updates about compliance, allow them to check standards, and post questions about the accreditation process.
- Use an internal online discussion board to help staff recognize existing compliance processes and to integrate new processes into everyday work.
- Use the ACC chapter to access accreditation policies and information about what happens before, during, after, and between surveys.
- Take note of any standards you need assistance with, and make an action plan to achieve compliance. You can use the Action Planning Worksheets at the back of each standards chapter to track your progress. (See the “Assess Compliance with the Standards” section for more information.)
- Seek answers to standards compliance questions online using the Standards Interpretation frequently asked questions (FAQs) at http://www.jointcommission.org/standards_information/jcfaq.aspx.
  - Save the link on your intranet or add it to your favorites list and encourage staff to regularly check the FAQs for laboratories or search by keyword.
  - When an FAQ provides helpful information, consider printing it out and inserting a copy of the FAQ in your manual, an accreditation binder, or an online discussion board to help clarify the intended rationale or requirement.
  - If you are unable to find the answer you need, accredited organizations may submit their own question using the online submission process on the FAQ page via your Joint Commission Connect extranet site (see the “Standards Questions” section for more information).
- Use resources and tools provided to all organizations on your Joint Commission Connect extranet site. In addition to E-dition, tools available on the site include the following:
Survey Planning Tools: Helpful information including a survey activity list, documentation list, and survey preparation notes to help you plan for the logistics and operational needs of an on-site survey.

Survey Activity Guide: A resource to help you prepare for survey, including an abstract of each survey activity with logistical needs, session objectives, an overview of the session, and suggested participants.

SAFER Matrix™ Information: A collection of resources to provide organizations with information related to the new Survey Analysis for Evaluating Risk™ (SAFER) process.

Intracycle Monitoring (ICM) Profile: To assist with continuous compliance efforts, this profile identifies high-risk areas and utilizes the FSA tool to identify related standards marked with a risk icon 🌈.

Leading Practice Library: Real-life solutions that have been successfully implemented by health care organizations and reviewed by Joint Commission standards experts.

Standards BoosterPaks*: Searchable guides intended to improve the understanding and consistency of standard interpretation by providing detailed information about a single standard or topic area associated with a high volume of inquiries or noncompliance in the health care field (for example, waived testing).

Targeted Solutions Tool*: An online application that guides health care organizations through a step-by-step process to accurately measure their organization’s actual performance, identify their barriers to excellent performance, and direct them to proven solutions that are customized to address their particular barriers.

Standards Interpretation: A landing page that allows organizations to submit questions and view FAQs related to the interpretation of standards.

Keep Current Standards Changes via Perspectives

It is strongly recommended that leadership and staff read Perspectives each month for the most up-to-date information about changes to standards and policies that are made throughout the year. Doing so allows you to learn about initiatives underway to support your efforts to achieve and sustain performance excellence. The current edition and the previous year of Perspectives are available on your Joint Commission Connect extranet site,
made available to organizations that are accredited or have applied for accreditation. Note the changes because your organization is responsible for meeting all applicable standards published in Perspectives.

- Check the Joint Commission website (https://www.jointcommission.org/accreditation/lab_standards_information.aspx) regularly for any revisions to laboratory standards published in Perspectives.
- Sign up for news and alerts, including standards changes, by clicking on “Sign up for News and Alerts” on the Joint Commission home page at http://www.jointcommission.org.
- Use the “What’s New” feature found on the blue navigation bar running along the top of the E-dition or at the front of the print manual to become familiar with changes that occurred since the last E-dition release.
- Check e-Alerts subscriptions on The Joint Commission website for new content or updates. For more information, visit https://www.jointcommission.org/ealerts/. Sign up for or update e-Alerts subscriptions at http://www.jointcommission.org/thickbox/NewsletterSignUp.aspx.

IV. Get Extra Help
All laboratories—regardless of size and scope of services—are entitled to ask for and receive additional support during the accreditation cycle. The following items provide a broad list of accreditation contacts at The Joint Commission and information and guidelines for maximizing your accreditation resources from Joint Commission Resources.

Getting Started with Accreditation
Organizations not yet accredited can call Business Development at 630-792-5781 for information about:
- The benefits of Joint Commission accreditation and optional certification
- Information about obtaining accreditation and optional certification
- Request for initial application

Account Executive
Accredited organizations can call their assigned account executive at 630-792-3007 for information or with questions about the following:
- Scheduling of surveys
Introduction: How The Joint Commission Can Help You Move Toward High Reliability

- Survey agenda or survey process
- Status of an Accreditation Survey Findings Report
- Content of an Accreditation Survey Findings Report
- ESC submission process
- Other survey activities
- Accessing and completing the Focused Standards Assessment

The name and contact information for your assigned account executive can be found on your Joint Commission Connect extranet site.

Contacting The Joint Commission
The Joint Commission’s main telephone number is 630-792-5000. The Joint Commission’s business hours are 8:30 A.M. to 5:00 P.M. central time, Monday through Friday.

Additional contact information can be found on The Joint Commission’s website at http://www.jointcommission.org. Access your Joint Commission Connect extranet site at https://customer.jointcommission.org/ (available to accredited organizations or those that have applied for accreditation) for organization-specific and general accreditation information and free resources.

Standards Questions
SIG provides answers to frequently asked questions online at https://www.jointcommission.org/standards_information/jcfaq.aspx. If you cannot find an answer to your question, accredited organizations may submit questions using the online submission process on the FAQ page or via your Joint Commission Connect extranet site (under “Resources and Tools”).

Requesting Permission to Copy Content from the Manual
Organizations accredited by The Joint Commission are allowed to make up to 10 copies of the print CAMLAB free of charge by e-mailing a request to permissions@jcrinc.com.
Call the Joint Commission Resources (JRC) Customer Service telephone number at 877-223-6866 (between 8:00 A.M. and 8:00 P.M. eastern time, Monday through Friday) or visit the JCR Store at http://jcrinc.com to purchase helpful compliance resources, including print copies of the manual, books and e-books, software programs, monthly newsletters, custom education, or consulting.
Patient Safety Systems (PS)

Introduction
The quality of care and the safety of patients are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, families, health care practitioners, staff, and laboratory leaders. This chapter exemplifies that commitment.

The intent of this “Patient Safety Systems” (PS) chapter is to provide laboratories with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission’s mission and its standards.

The Joint Commission partners with accredited laboratories to improve health care systems to protect patients. The first obligation of health care is to “do no harm.” Therefore, this chapter is focused on the following three guiding principles:
1. Aligning existing Joint Commission standards with daily work in order to engage patients and staff throughout the health care system, at all times, on reducing harm.
2. Assisting laboratories with advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes.
3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame.

Quality and safety are inextricably linked. Quality in health care is the degree to which its processes and results meet or exceed the needs and desires of the people it serves. Those needs and desires include safety.

The components of a quality management system should include the following:
- Ensuring reliable processes
- Decreasing variation and defects (waste)

Focusing on achieving better outcomes
Using evidence to ensure that a service is satisfactory

Patient safety emerges as a central aim of quality. *Patient safety*, as defined by the World Health Organization, is the prevention of errors and adverse effects to patients that are associated with health care. Safety is what patients, families, staff, and the public expect from Joint Commission–accredited laboratories. While patient safety events may not be completely eliminated, harm to patients can be reduced, and the goal is always zero harm. This chapter describes and provides approaches and methods that may be adapted by a laboratory that aims to increase the reliability of its complex systems while making visible and removing the risk of patient harm. Joint Commission–accredited laboratories should be continually focused on eliminating systems failures and human errors that may cause harm to patients, families, and staff.\(^1\)\(^2\)

The ultimate purpose of The Joint Commission’s accreditation process is to enhance quality of care and patient safety. Each requirement or standard, the survey process, the Sentinel Event Policy, and other Joint Commission initiatives are designed to help laboratories reduce variation, reduce risk, and improve quality. Laboratories should have an integrated approach to patient safety so that high levels of safe patient care can be provided for every patient in every care setting and service.

Laboratories are complex environments that depend on strong leadership to support an integrated patient safety system that includes the following:

- Safety culture
- Validated methods to improve processes and systems
- Standardized ways for interdisciplinary teams to communicate and collaborate
- Safely integrated technologies

In an integrated patient safety system, staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from their patient safety events, including close calls and other system failures that have not yet led to patient harm.

**What Does This Chapter Contain?**

The “Patient Safety Systems” (PS) chapter is intended to help inform and educate laboratories about the importance and structure of an integrated patient safety system. **This chapter describes how existing requirements can be applied to achieve improved**
**Patient Safety Systems**

**continued on next page**

A number of Joint Commission standards. Standards cited in this chapter are formatted with the standard number in boldface type and are accompanied by language that summarizes the standard. For the full text of a standard and its element(s) of performance (EP), please see the Appendix.

**Sidebar 1. Key Terms to Understand**

- **Patient safety event**: An event, incident, or condition that could have resulted or did result in harm to a patient.
- **Adverse event**: A patient safety event that resulted in harm to a patient.
- **Sentinel event**: A subcategory of Adverse Events, a Sentinel Event is a patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in any of the following:
  - Death
  - Permanent harm
  - Severe temporary harm

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†For a list of specific patient safety events that are also considered sentinel events, see page SE-1 in the “Sentinel Events” (SE) chapter of this manual.
Sidebar 1 (continued)

- Close call or “near miss,” “no harm,” or “good catch”: A patient safety event that did not cause harm as defined by the term sentinel event.
- Hazardous (or “unsafe”) condition(s): A circumstance (other than a patient’s own disease process or condition) that increases the probability of an adverse event.

Note: It is impossible to determine if there are practical prevention or mitigation countermeasures available without first doing an event analysis. An event analysis will identify systems-level vulnerabilities and weaknesses and the possible remedial or corrective actions that can be implemented.

Becoming a Learning Organization

The need for sustainable improvement in patient safety and the quality of care has never been greater. One of the fundamental steps to achieving and sustaining this improvement is to become a learning organization. A learning organization is one in which people learn continuously, thereby enhancing their capabilities to create and innovate.³ Learning organizations uphold five principles: team learning, shared visions and goals, a shared mental model (that is, similar ways of thinking), individual commitment to lifelong learning, and systems thinking.³ In a learning organization, patient safety events are seen as opportunities for learning and improvement.⁴ Therefore, leaders in learning organizations adopt a transparent, nonpunitive approach to reporting so that the organization can report to learn and can collectively learn from patient safety events. In order to become a learning organization, a laboratory must have a fair and just safety culture, a strong reporting system, and a commitment to put that data to work by driving improvement. Each of these require the support and encouragement of laboratory leaders.

Leaders, staff, licensed independent practitioners, and patients in a learning organization realize that every patient safety event (from close calls to events that cause major harm to patients) must be reported.⁴⁸ When patient safety events are continuously reported, experts within the laboratory can define the problem, identify solutions, achieve sustainable results, and disseminate the changes or lessons learned to the rest of the
laboratory. In a learning organization, the laboratory provides staff with information regarding improvements based on reported concerns. This helps foster trust that encourages further reporting.

The Role of Laboratory Leaders in Patient Safety

Laboratory leaders provide the foundation for an effective patient safety system by doing the following:

- Promoting learning
- Motivating staff to uphold a fair and just safety culture
- Providing a transparent environment in which quality measures and patient harms are freely shared with staff
- Modeling professional behavior
- Removing intimidating behavior that might prevent safe behaviors
- Providing the resources and training necessary to take on improvement initiatives

For these reasons, many of the standards that are focused on the laboratory’s patient safety system appear in the Joint Commission’s Leadership (LD) standards, including Standard LD.04.04.05 (which focuses on having a laboratorywide, integrated patient safety program within performance improvement activities).

Without the support of laboratory leaders, laboratorywide changes and improvement initiatives are difficult to achieve. Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change their behaviors fail in the absence of leadership managing the change. Thus, leadership should take on a long-term commitment to transform the laboratory.

Safety Culture

A strong safety culture is an essential component of a successful patient safety system and is a crucial starting point for laboratories striving to become learning organizations. In a strong safety culture, the laboratory has an unrelenting commitment to safety and to do no harm. Among the most critical responsibilities of laboratory leaders is to establish and maintain a strong safety culture within their laboratory. The Joint Commission’s standards address safety culture in Standard LD.03.01.01, which requires leaders to create and maintain a culture of safety and quality throughout the laboratory.
Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing

The safety culture of a laboratory is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the laboratory’s commitment to quality and patient safety. Laboratories that have a robust safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures. Laboratories will have varying levels of safety culture, but all should be working toward a safety culture that has the following qualities:

- Staff and leaders that value transparency, accountability, and mutual respect.
- Safety as everyone’s first priority.
- Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to laboratory leadership by staff, patients, and families for the purpose of fostering risk reduction.
- Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed. Staff do not view close calls as evidence that the system prevented an error but rather as evidence that the system needs to be further improved to prevent any defects.
- Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events. Staff know that their leaders will focus not on blaming providers involved in errors but on the systems issues that contributed to or enabled the patient safety event.
- By reporting and learning from patient safety events, staff create a learning organization.

A safety culture operates effectively when the laboratory fosters a cycle of trust, reporting, and improvement. In laboratories that have a strong safety culture, health care providers trust their coworkers and leaders to support them when they identify and report a patient safety event. When trust is established, staff are more likely to report patient safety events, and laboratories can use these reports to inform their improvement efforts. In the trust-report-improve cycle, leaders foster trust, which enables staff to report, which enables the laboratory to improve. In turn, staff see that their reporting contributes to actual improvement, which bolsters their trust. Thus, the trust-report-improve cycle reinforces itself. (See Figure 1.)
In the trust-report-improve cycle, trust promotes reporting, which leads to improvement, which in turn fosters trust.

Leaders need to ensure that intimidating or unprofessional behaviors within the laboratory are addressed, so as not to inhibit others from reporting safety concerns. Leaders should both educate staff and hold them accountable for professional behavior. This includes the adoption and promotion of a code of conduct that defines acceptable behavior as well as behaviors that undermine a culture of safety. The Joint Commission’s Standard **LD.03.01.01**, EP 4, requires that leaders develop such a code.

Intimidating and disrespectful behaviors disrupt the culture of safety and prevent collaboration, communication, and teamwork, which is required for safe and highly reliable patient care. Disrespect is not limited to outbursts of anger that humiliate a member of the health care team; it can manifest in many forms, including the following:4,12,17

- Inappropriate words (profane, insulting, intimidating, degrading, humiliating, or abusive language)
- Shaming others for negative outcomes
- Unjustified negative comments or complaints about another provider’s care
- Refusal to comply with known and generally accepted practice standards, the refusal of which may prevent other providers from delivering quality care

**Figure 1. The Trust-Report-Improve Cycle with Robust Process Improvement® (RPI®)**
Not working collaboratively or cooperatively with other members of the interdisciplinary team

Creating rigid or inflexible barriers to requests for assistance or cooperation

Not returning pages or calls promptly

These issues are still occurring in laboratories nationwide. Of 4,884 respondents to a 2013 survey by the Institute for Safe Medication Practices (ISMP), 73% reported encountering negative comments about colleagues or leaders during the previous year. In addition, 68% reported condescending language or demeaning comments or insults; while 77% of respondents said they had encountered reluctance or refusal to answer questions or return calls. Further, 69% report that they had encountered impatience with questions or the hanging up of the phone.

Nearly 50% of the respondents indicated that intimidating behaviors had affected the way they handle medication order clarifications or questions, including assuming that an order was correct in order to avoid interaction with an intimidating coworker. Moreover, 11% said they were aware of a medication error during the previous year in which behavior that undermines a culture of safety was a contributing factor. The respondents included nurses, physicians, pharmacists, and quality/risk management personnel.

Only 50% of respondents indicated that their organizations had clearly defined an effective process for handling disagreements with the safety of an order. This is down from 60% of respondents to a similar ISMP survey conducted in 2003, which suggests that this problem is worsening. While these data are specific to medication safety, their lessons are broadly applicable: Behaviors that undermine a culture of safety have an adverse effect on quality and patient safety.

**A Fair and Just Safety Culture**

A fair and just safety culture is needed for staff to trust that they can report patient safety events without being treated punitively. In order to accomplish this, laboratories should provide and encourage the use of a standardized reporting process for staff to report patient safety events. This is also built into the Joint Commission’s standards at Standard **LD.04.04.05**, EP 6, which requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments. Reporting enables both proactive and reactive risk reduction. *Proactive risk reduction* solves problems before patients are harmed, and *reactive risk reduction* attempts to prevent the recurrence of problems that have already caused patient harm.
A fair and just culture takes into account that individuals are human, fallible, and capable of mistakes, and that they work in systems that are often flawed. In the most basic terms, a fair and just culture holds individuals accountable for their actions but does not punish individuals for issues attributed to flawed systems or processes. Refer to Standard LD.04.04.05, EP 6, which requires that staff are held accountable for their responsibilities.

It is important to note that for some actions for which an individual is accountable, the individual should be held culpable and some disciplinary action may then be necessary. (See Sidebar 2, below, for a discussion of tools that can help leaders determine a fair and just response to a patient safety event.) However, staff should never be punished or ostracized for reporting the event, close call, hazardous condition, or concern.

Sidebar 2. Assessing Staff Accountability

The aim of a safety culture is not a "blame-free" culture but one that balances learning with accountability. To achieve this, it is essential that leaders assess errors and patterns of behavior in a manner that is applied consistently, with the goal of eliminating behaviors that undermine a culture of safety. There has to exist within the laboratory a clear, equitable, and transparent process for recognizing and separating the blameless errors that fallible humans make daily from the unsafe or reckless acts that are blameworthy. There are a number of sources for information (some of which are listed immediately below) that provide rationales, tools, and techniques that will assist a laboratory in creating a formal decision process to determine what events should be considered blameworthy and require individually directed action in addition to systems-level corrective actions. The use of a formal process will reinforce the culture of safety and demonstrate the laboratory’s commitment to transparency and fairness.

Reaching answers to these questions requires an initial investigation into the patient safety event to identify contributing factors. The use of the Incident Decision Tree (adapted by the United Kingdom’s National Patient Safety Agency from James Reason's culpability matrix) or other formal decision process can help make determinations of culpability more transparent and fair.

References


Data Use and Reporting Systems
An effective culture of safety is evidenced by a robust reporting system and use of measurement to improve. When laboratories adopt a transparent, nonpunitive approach to reports of patient safety events or other concerns, the laboratory begins reporting to learn—and to learn collectively from adverse events, close calls, and hazardous conditions. This section focuses on data from reported patient safety events. Laboratories should note that this is but one type of data among many that should be collected and used to drive improvement.

When there is continuous reporting for adverse events, close calls, and hazardous conditions, the laboratory can analyze the patient safety events, change the process or system to improve safety, and disseminate the changes or lessons learned to the rest of the laboratory.20–24

In addition to those mentioned earlier in this chapter, a number of standards relate to the reporting of safety information, including Performance Improvement (PI) Standard PL.01.01.01, which requires laboratories to collect data to monitor their performance,
Patient Safety Systems

and Standard **LD.03.02.01**, which requires laboratories to use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Laboratories can engage frontline staff in internal reporting in a number of ways, including the following:
- Create a nonpunitive approach to patient safety event reporting
- Educate staff on identifying patient safety events that should be reported
- Provide timely feedback regarding actions taken on patient safety events

**Effective Use of Data**

**Collecting Data**

When laboratories collect data or measure staff compliance with evidence-based care processes or patient outcomes, they can manage and improve those processes or outcomes and, ultimately, improve patient safety. The effective use of data enables laboratories to identify problems, prioritize issues, develop solutions, and track to determine success. Objective data can be used to support decisions, influence people to change their behaviors, and to comply with evidence-based care guidelines.

The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) both require laboratories to collect and use data related to certain patient care outcomes and patient harms. Some key Joint Commission standards related to data collection and use require laboratories to do the following:
- Collect information to monitor conditions in the environment (Standard **EC.04.01.01**)
- Identify risks for acquiring and transmitting infections (Standard **IC.01.03.01**)
- Use data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality (Standard **LD.03.02.01**)
- Have a laboratorywide, integrated patient safety program within their performance improvement activities (Standard **LD.04.04.05**)
- Collect data to monitor their performance (Standard **PI.01.01.01**)
- Improve performance on an ongoing basis (Standard **PI.03.01.01**)

**Analyzing Data**

Effective data analysis can enable a laboratory to “diagnose” problems within its system similar to the way one would diagnose a patient’s illness based on symptoms, health history, and other factors. Turning data into information is a critical competency of a
learning organization and of effective management of change. When the right data are collected and appropriate analytic techniques are applied, it enables the laboratory to monitor the performance of a system, detect variation, and identify opportunities to improve. This can help the laboratory not only understand the current performance of laboratory systems but also can help it predict its performance going forward.

Analyzing data with tools such as run charts, statistical process control (SPC) charts, and capability charts helps a laboratory determine what has occurred in a system and provides clues as to why the system responded as it did. Table 1, following, describes and compares examples of these tools. Please note that several types of SPC charts exist; this discussion focuses on the XmR chart, which is the most commonly used.
# Table 1. Defining and Comparing Analytical Tools

<table>
<thead>
<tr>
<th>Tool</th>
<th>When to Use</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run Chart</td>
<td>- When the laboratory needs to identify variation within a system</td>
<td><img src="image1" alt="Arrival Time to Diagnostic Evaluation Time" /></td>
</tr>
<tr>
<td></td>
<td>- When the laboratory needs a simple and straightforward analysis of a system</td>
<td><img src="image2" alt="Tobacco Use Treatment Provided or Offered" /></td>
</tr>
<tr>
<td></td>
<td>- As a precursor to an SPC chart</td>
<td><img src="image3" alt="Specification Limits (+ Customer Requirements)" /></td>
</tr>
<tr>
<td>Statistical Process Control Chart</td>
<td>- When the laboratory needs to identify variation within a system and find indicators of why the variation occurred</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- When the laboratory needs a more detailed and in-depth analysis of a system</td>
<td>In the example above, the curve at the top of the chart indicates a process that is only partly capable of meeting requirements. The curve at the bottom of the chart shows a process that is fully capable.</td>
</tr>
<tr>
<td>Capability Chart</td>
<td>- When the laboratory needs to determine whether a process will function as expected, according to requirements or specifications</td>
<td></td>
</tr>
</tbody>
</table>

In the example above, the curve at the top of the chart indicates a process that is only partly capable of meeting requirements. The curve at the bottom of the chart shows a process that is fully capable.
Sources:

Using Data to Drive Improvement
After data has been turned into information, leadership should ensure the following (per the requirements shown):27–29
- Information is presented in a clear manner (Standard LD.03.04.01, EP 3)
- Information is shared with the appropriate groups throughout the laboratory (from the front line to the board) (Standards LD.03.04.01, LD.04.04.05)
- Opportunities for improvement and actions to be taken are clearly articulated (Standards LD.03.05.01, EP 4; LD.04.04.01)
- Improvements are celebrated or recognized

A Proactive Approach to Preventing Harm
Proactive risk reduction prevents harm before it reaches the patient. By engaging in proactive risk reduction, a laboratory can correct process problems in order to reduce the likelihood of experiencing adverse events.

In a proactive risk assessment the laboratory evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. A proactive risk assessment increases understanding within the laboratory about the complexities of process design and management—and what could happen if the process fails.

When conducting a proactive risk assessment, laboratories should prioritize high-risk, high-frequency areas. Areas of risk are identified from internal sources such as ongoing monitoring of the environment, results of previous proactive risk assessments, from results of data collection activities. Risk assessment tools should be accessed from credible external sources such as a Sentinel Event Alert, nationally recognized risk assessment tools, and peer review literature. Benefits of a proactive approach to patient safety includes increased likelihood of the following:
- Identification of actionable common causes
- Avoidance of unintended consequences
Identification of commonalities across departments/services/units
Identification of system solutions

Hazardous (or unsafe) conditions provide an opportunity for a laboratory to take a proactive approach to reduce harm. Laboratories also benefit from identifying hazardous conditions while designing any new process that could impact patient safety. A hazardous condition is defined as any circumstance that increases the probability of a patient safety event. A hazardous condition may be the result of a human error or violation, may be a design flaw in a system or process, or may arise in a system or process in changing circumstances.‡ A proactive approach to such conditions should include an analysis of the systems and processes in which the hazardous condition is found, with a focus on conditions that preceded the hazardous condition. (See Sidebar 3.)

A proactive approach to hazardous conditions should include an analysis of the related systems and processes, including the following aspects:§

- **Preconditions.** Examples include hazardous (or unsafe) conditions in the environment of care (such as noise, clutter, wet floors and so forth), inadequate staffing levels, an operator who is impaired or inadequately trained.
- **Supervisory influences.** Examples include inadequate supervision, planned inappropriate operations, failure to address a known problem, authorization of activities that are known to be hazardous.
- **Organizational influences.** Examples include inadequate staffing, inadequate policies, lack of strategic risk assessment.

The Joint Commission addresses proactive risk assessments at Standard **LD.04.04.05**, EP 10, which requires laboratories to select one high-risk process and conduct a proactive risk assessment at least every 18 months.

Laboratories should recognize that this standard represents a minimum requirement. Laboratories working to become learning organizations are encouraged to exceed this requirement by constantly working to proactively identify risk.

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‡Human errors are typically skills based, decision based, or knowledge based; whereas violations could be either routine or exceptional (intentional or negligent). Routine violations tend to include habitual “bending of the rules,” often enabled by management. A routine violation may break established rules or policies, and yet be a common practice within an organization. An exceptional violation is a willful behavior outside the norm that is not condoned by management, engaged in by others, and not part of the individual’s usual behavior. **Source:** Diller T, et al. The human factors analysis classification system (HFACS) applied to health care. *Am J Med Qual.* 2014 May–Jun;29(3):181–190.
Sidebar 3. Strategies for an Effective Risk Assessment

Although several methods could be used to conduct a proactive risk assessment, the following steps comprise one approach:

- Describe the chosen process (for example, through the use of a flowchart).
- Identify ways in which the process could break down or fail to perform its desired function, which are often referred to as “failure modes.”
- Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
- Prioritize the potential process breakdowns or failures.
- Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
- Design or redesign the process and/or underlying systems to minimize the risk of the effects on patients.
- Test and implement the newly designed or redesigned process.
- Monitor the effectiveness of the newly designed or redesigned process.

Tools for Conducting a Proactive Risk Assessment

A number of tools are available to help laboratories conduct a proactive risk assessment. One of the best known of these tools is the Failure Modes and Effects Analysis (FMEA). An FMEA is used to prospectively examine how failures could occur during high-risk processes and, ultimately, how to prevent them. The FMEA asks “What if?” to explore what could happen if a failure occurs at particular steps in a process.31

Laboratories have other tools they can consider using in their proactive risk assessment. Some examples include the following:

Potential problem analysis (PPA) is a systematic method for determining what could go wrong in a plan under development. The problem causes are rated according to their likelihood of occurrence and the severity of their consequences. Visit https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools for more information.

Process decision program chart (PDPC) provides a systematic means of finding errors with a plan while it is being created. After potential issues are found, preventive measures are developed, allowing the problems to either be avoided or a contingency plan to be in place should the error occur. Visit http://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/process-decision-program-chart.

Encouraging Patient Activation
To achieve the best outcomes, patients and families must be more actively engaged in decisions about their health care and must have broader access to information and support. Patient activation is inextricably intertwined with patient safety. Activated patients are less likely to experience harm and unnecessary hospital readmissions. Patients who are less activated suffer poorer health outcomes and are less likely to follow their provider’s advice.32,33

A patient-centered approach to care can help laboratories assess and enhance patient activation. Achieving this requires leadership engagement in the effort to establish patient-centered care as a top priority throughout the laboratory. This includes adopting the following principles:34

- Patient safety guides all decision making.
- Patients and families are partners at every level of care.
- Patient- and family-centered care is verifiable, rewarded, and celebrated.
- The licensed independent practitioner responsible for the patient’s care, or his or her designee, discloses to the patient and family any unanticipated outcomes of care, treatment, and services.
- Though Joint Commission standards do not require apology, evidence suggests that patients benefit—and are less likely to pursue litigation—when physicians disclose harm, express sympathy, and apologize.
- Staffing levels are sufficient, and staff has the necessary tools and skills.
- The laboratory has a focus on measurement, learning, and improvement.
Staff and licensed independent practitioners must be fully engaged in patient- and family-centered care as demonstrated by their skills, knowledge, and competence in compassionate communication.

Laboratories can adopt a number of strategies to support and improve patient activation, including promoting culture change, adopting transitional care models, and leveraging health information technology capabilities.

Beyond Accreditation: The Joint Commission Is Your Patient Safety Partner

To assist laboratories on their journey toward creating highly reliable patient safety systems, The Joint Commission provides many resources, including the following:

- **Office of Quality and Patient Safety**: An internal Joint Commission department that offers laboratories guidance and support when they experience a sentinel event. Laboratories can call the Sentinel Event Hotline (630-792-3700) to clarify whether a patient safety event is considered to be a sentinel event (and therefore reviewable) or to discuss any aspect of the Sentinel Event Policy. The Office of Quality and Patient Safety assesses the thoroughness and credibility of a laboratory’s comprehensive systematic analysis as well as the action plan to help the laboratory prevent the hazardous or unsafe conditions from occurring again.

- **Joint Commission Center for Transforming Healthcare**: A Joint Commission not-for-profit affiliate that offers highly effective, durable solutions to health care’s most critical safety and quality problems to help laboratories transform into high reliability organizations. For specific quality and patient problems, the Center’s Targeted Solutions Tool® (TST®) guides laboratories through a step-by-step process to measure their laboratory’s performance, identify barriers to excellence, and direct them to proven solutions. To date, a TST has been developed for each of the following: hand hygiene, hand-off communications, and wrong-site surgery. For more information, visit http://www.centerfortransforminghealthcare.org.

- **Standards Interpretation Group**: An internal Joint Commission department that helps laboratories with their questions about Joint Commission standards. First, laboratories can see if other laboratories have asked the same question by accessing the Standards FAQs at http://www.jointcommission.org/standards_information/jcfaq.aspx. Thereafter, laboratories can submit questions about standards to the Standards Interpretation Group by completing an online form at https://web.jointcommission.org/sigsubmission/sigonlineform.aspx.
National Patient Safety Goals: The Joint Commission’s yearly patient safety requirements based on data obtained from the Joint Commission’s Sentinel Event Database and recommended by a panel of patient safety experts. (For a list of the current National Patient Safety Goals, go to http://www.jointcommission.org/standards_information/npsgs.)

Sentinel Event Alert: The Joint Commission’s periodic alerts with timely information about similar, frequently reported sentinel events, including root causes, applicable Joint Commission requirements, and suggested actions to prevent a particular sentinel event. (For archives of previously published Sentinel Event Alerts, go to http://www.jointcommission.org/sentinel_event.aspx.)

Quick Safety: Quick Safety is a monthly newsletter that outlines an incident, topic, or trend in health care that could compromise patient safety. http://www.jointcommission.org/quick_safety.aspx?archive=y

Core Measure Solution Exchange*: Available for accredited or certified laboratories through the Joint Commission Connect™ extranet, laboratories can search a database of over two hundred success stories from accredited health care organizations that have attained excellent performance on core measures, including accountability measures.

Joint Commission Resources: A Joint Commission not-for-profit affiliate that produces books and periodicals, holds conferences, provides consulting services, and develops software products (including AMP*, Tracers with AMP*, E-dition*, ECM Plus*, and CMSAccess®) for accreditation and survey readiness. (For more information, visit http://www.jcrinc.com.)

Webinars and podcasts: The Joint Commission and its affiliate, Joint Commission Resources, offer free webinars and podcasts on various accreditation and patient safety topics.

Speak Up™ program: The Joint Commission’s campaign to educate patients about health care processes and potential safety issues and encourage them to speak up whenever they have questions or concerns about their safety. (For more information and patient education resources, go to http://www.jointcommission.org/speakup.)

Standards BoosterPaks™: Available for accredited or certified laboratories through Joint Commission Connect, laboratories can access BoosterPaks that provide detailed information about a single standard or topic area that has been associated with a high volume of inquiries or noncompliance scores. Recent standards BoosterPack topics have included credentialing and privileging in nonlaboratory settings, waived
testing, restraint and seclusion, management of hazardous waste, environment of care (including Standards EC.04.01.01, EC.04.01.03, and EC.04.01.05), and sample collection.

- **Leading Practice Library**: Available for accredited or certified laboratories through Joint Commission Connect, laboratories can access an online library of solutions to help improve safety. The searchable documents in the library are actual solutions that have been successfully implemented by laboratories and reviewed by Joint Commission standards experts.

- **Joint Commission web portals**: Through The Joint Commission website, laboratories can access web portals with a repository of resources from The Joint Commission, the Joint Commission Center for Transforming Healthcare, Joint Commission Resources, and Joint Commission International on the following topics:
  - Emergency management: http://www.jointcommission.org/emergency_management.aspx
  - Workplace violence prevention resources: https://www.jointcommission.org/workplace_violence.aspx

**References**


Appendix. Key Patient Safety Requirements
A number of Joint Commission standards have been discussed in the “Patient Safety Systems” (PS) chapter. However, many Joint Commission requirements address issues related to the design and management of patient safety systems, including the following examples.

Environment of Care (EC)

Standard EC.04.01.01
The laboratory collects information to monitor conditions in the environment.

Elements of Performance for EC.04.01.01

1. The laboratory establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
   - Injuries to patients or others within the laboratory
   - Occupational illnesses and staff injuries
   - Incidents of damage to its property or the property of others in locations it controls
   - Security incidents involving patients, staff, or others in locations it controls
   - Hazardous materials and waste spills and exposures
   - Fire safety management problems, deficiencies, and failures
   - Laboratory equipment management problems, failures, and use errors
   - Utility systems management problems, failures, or use errors

   Note 1: All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.

   Note 2: Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve laboratory services, or to prevent similar incidents, are not lost as a result of following the legal process.

The laboratory reports and investigates the following:

3. Injuries occurring in the laboratory.
4. Occupational illnesses and staff injuries.
5. Incidents of damage to its property or the property of others in locations it controls.
6. Security incidents involving patients, staff, or others in locations it controls.
8. Hazardous materials and waste spills and exposures.
10. Laboratory equipment management problems, failures, and use errors.
11. Utility systems management problems, failures, or use errors.
15. Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan’s objectives, scope, performance, and effectiveness.

**Standard EC.04.01.03**
The laboratory analyzes identified environment of care issues.

**Element of Performance for EC.04.01.03**
2. The laboratory uses the results of data analysis to identify opportunities to resolve environmental safety issues.

**Standard EC.04.01.05**
The laboratory improves its environment of care.

**Element of Performance for EC.04.01.05**
1. The laboratory takes action on the identified opportunities to resolve environmental safety issues.

**Infection Prevention and Control (IC)**

**Standard IC.01.03.01**
The laboratory identifies its risks for acquiring and transmitting infections.
Elements of Performance for IC.01.03.01

1. The laboratory identifies its infection risks based on the laboratory services it provides. R

3. The laboratory prioritizes its identified risks for acquiring and transmitting infections. These prioritized risks are documented. R

Leadership (LD)

Standard LD.03.01.01
Leaders create and maintain a culture of safety and quality throughout the laboratory.

Elements of Performance for LD.03.01.01

1. Leaders regularly evaluate the culture of safety and quality.

2. Leaders prioritize and implement changes identified by the evaluation.

4. Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.

5. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

Standard LD.03.02.01
The laboratory uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Elements of Performance for LD.03.02.01

1. Leaders set expectations for using data and information to improve the safety and quality of laboratory services. R

2. Leaders are able to describe how data and information are used to create a culture of safety and quality. R

3. The laboratory uses processes to support systematic data and information use. R

4. Leaders provide the resources needed for data and information use, including staff, equipment, and information systems. R
5. The laboratory uses data and information in decision making that supports the safety and quality of laboratory services. *(See also PI.02.01.01, EP 8)*

6. The laboratory uses data and information to identify and respond to internal and external changes in the environment.

7. Leaders evaluate how effectively data and information are used throughout the laboratory.

**Standard LD.03.04.01**

The laboratory communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

**Elements of Performance for LD.03.04.01**

1. Communication processes foster the safety of the patient and the quality of care.

2. Leaders are able to describe how communication supports a culture of safety and quality.

3. Communication is designed to meet the needs of internal and external users.

4. Leaders provide the resources required for communication, based on the needs of patients, staff, and management.

5. Communication supports safety and quality throughout the laboratory. *(See also LD.04.04.05, EP 6)*

6. When changes in the environment occur, the laboratory communicates those changes effectively.

7. Leaders evaluate the effectiveness of communication methods.

**Standard LD.03.05.01**

Leaders implement changes in existing processes to improve the performance of the laboratory.

**Elements of Performance for LD.03.05.01**

4. Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training.
Standard LD.04.04.01
Leaders establish priorities for performance improvement. (Refer to the “Performance Improvement” [PI] chapter.)

Elements of Performance for LD.04.04.01
1. Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3)
2. Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 7, 8, and 23)
3. Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.
4. Performance improvement occurs laboratorywide.

Standard LD.04.04.05
The laboratory manages safety issues.

Elements of Performance for LD.04.04.05
6. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.04.01, EP 5; LD.04.04.03, EP 5)

Note: This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.

7. The leaders define patient safety event and communicate this definition throughout the organization.

Note: At a minimum, the organization’s definition includes those events subject to review in the “Sentinel Events” (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a close call or near miss.

8. The laboratory conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the “Sentinel Events” (SE) chapter of this manual.
11. To improve safety, the laboratory analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. *(See also LD.04.04.03, EP 5)*

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**Quality System Assessment for Nonwaived Testing (QSA)**

**Standard QSA.01.01.01**

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)—approved proficiency testing programs for all regulated analytes.

**Note:** *This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).*

**Elements of Performance for QSA.01.01.01**

1. © The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)—approved proficiency testing program* that meets regulatory requirements for variety and frequency of testing. *(See also LD.04.05.07, EP 4) R*

2. The laboratory authorizes the proficiency testing program to release all data required to determine the laboratory’s compliance for proficiency testing and makes proficiency testing results available to the public as required in the Public Health Service Act, Section 353(f)(3)(F). R

3. The laboratory uses a proficiency testing program for each regulated analyte performed. R

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For information on current proficiency testing providers, see http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp.

For more information on proficiency testing, see http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.
4. The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program before the conclusion of a full calendar year, it notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission before this change is made.

5. For each specialty, subspecialty, analyte, or test, the laboratory’s proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.

**Note 1:** Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), Subpart H, include the following:

- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing
- Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing
- Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.
- Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.

**Note 2:** Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.

(For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

6. The laboratory’s proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation.
Note: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.

7. Individuals who examine gynecologic preparations participate in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing and satisfactory performance criteria.

Note 1: For an individual who fails an annual proficiency testing event (less than 90% on a 10-slide proficiency test), the laboratory schedules a retesting event that takes place not more than 45 days after the receipt of the notification of failure. Steps of retesting include the following:

- A 10-slide retest (event #2), performed within 2 hours, in which a score of 90% is acceptable
- For an individual who fails the 10-slide retest (event #2), the laboratory provides remedial training and education in the area of failure and has evidence that all patient gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide proficiency test (event #3), performed within 4 hours, in which a score of 90% is acceptable.
- An individual who fails the last 20-slide proficiency test (event #3) ceases examining gynecologic slide preparations immediately upon notification of test failures and may not resume examining gynecologic slides until the laboratory has evidence that the individual obtained at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until the individual is retested with another 20-slide proficiency test and scores at least 90%.
- This final cycle continues until the individual successfully participates in another 20-slide proficiency test.

Note 2: Unexcused absence by an individual for a retest will result in a test failure.

(See also QSA.01.02.01, EP 5)
Accreditation Participation Requirements (APR)

Overview
This chapter consists of specific requirements for participation in the accreditation process and for maintaining an accreditation award.

For a laboratory seeking accreditation for the first time, compliance with most of the Accreditation Participation Requirements (APRs) is assessed during the initial survey, including the Early Survey Policy Options. Please note that APR.09.01.01 and APR.09.02.01 are not assessed during the initial survey. For the accredited laboratory, compliance with the APRs is assessed throughout the accreditation cycle through on-site surveys, the Focused Standards Assessment (FSA), Evidence of Standards Compliance (ESC), and periodic updates of laboratory-specific data and information. Laboratories are either compliant or not compliant with the APRs. When a laboratory does not comply with an APR, the laboratory will be assigned a Requirement for Improvement (RFI) in the same context that noncompliance with a standard or element of performance generates an RFI. However, refusal to permit performance of a survey (APR.02.01.01) will lead to a denial of accreditation. Falsification of information (APR.01.02.01) will lead to preliminary denial of accreditation. All RFIs can impact the accreditation decision and follow-up requirements, as determined by established accreditation decision rules. Failure to resolve an RFI can ultimately lead to loss of accreditation.
Chapter Outline

I. Submission of Information to The Joint Commission
   A. Timely Submission of Information (APR.01.01.01)
   B. Accuracy of Information (APR.01.02.01)
   C. Changes in Information (APR.01.03.01)

II. Performance of Survey
   A. Performance of Survey at The Joint Commission’s Discretion (APR.02.01.01)

III. Focused Standards Assessment (FSA)
   A. Participating in the Focused Standards Assessment (APR.03.01.01)

IV. Performance Measurement—Not applicable to laboratories

V. External Evaluations
   A. Sharing Results of External Evaluations with The Joint Commission (APR.05.01.01)

VI. Accreditation-Related Consulting Services
   A. Prohibiting Use of Joint Commission Employees (APR.06.01.01)

VII. Survey Observations
   A. Joint Commission Management and Leadership Observing Surveys (APR.07.01.01)

VIII. Representation of Accreditation Status
   A. Accurately Representing Accreditation Status (APR.08.01.01)

IX. Reporting of Safety and Quality Concerns
   A. Notifying the Public about Reporting Safety and Quality Concerns (APR.09.01.01)
   B. Notifying Individuals Who Provide Care, Treatment, or Services about Reporting Safety and Quality Concerns (APR.09.02.01)
   C. Adhering to Joint Commission Guidelines for Describing Information in the Quality Report (APR.09.03.01)
   D. Providing Care, Treatment, Services, and an Environment That Pose No Risk of an Immediate Threat to Health or Safety (APR.09.04.01)

X. Federal Requirements
   A. Complying with Proficiency Testing (APR.10.03.01)
Requirements, Rationales, and Elements of Performance

APR.01.01.01
The laboratory submits information to The Joint Commission as required.

Element of Performance for APR.01.01.01

1. The laboratory meets all requirements for timely submissions of data and information to The Joint Commission.

   Note 1: The Joint Commission will impose the following consequence for failure to comply with this APR:

   If the laboratory consistently fails to meet the requirements for the timely submission of data and information to The Joint Commission, the laboratory will be required to undergo an Accreditation with Follow-up Survey. Failure to resolve this issue at the time of the Accreditation with Follow-up Survey may result in an accreditation decision change.

   Note 2: The proposed consequences address only compliance with the requirement itself. They do not address the content of the laboratory’s submissions to The Joint Commission. For example, if information in a laboratory’s electronic application for accreditation (E-App) leads to inaccuracies in the appropriate length of the survey and a longer survey is required, the laboratory will incur the additional costs of the longer survey. In addition, if there is evidence that the laboratory has intentionally falsified the information submitted to The Joint Commission, the requirement at APR.01.02.01, EP 1 and its consequences will apply. (See also APR.01.02.01, EP 1)

APR.01.02.01
The laboratory provides accurate information throughout the accreditation process.

Rationale for APR.01.02.01
The Joint Commission requires each laboratory seeking accreditation to engage in the accreditation process in good faith. Sound business practices require transparency in all reporting procedures to ensure the safety of the public and the people who work in the laboratory. Any laboratory that fails to participate in good faith by falsifying information or by failing to exercise due care and diligence to ensure the accuracy of such information may have its accreditation denied or removed by The Joint Commission.
Element of Performance for APR.01.02.01

1. The laboratory provides accurate information throughout the accreditation process. (See also APR.01.01.01, EP 1; QSA.01.04.01, EP 1)

**Note 1:** Information may be received in any of the following ways:
- Provided verbally
- Obtained through direct observation by, or in an interview or any other type of communication with, a Joint Commission employee
- Derived from documents supplied by the laboratory to The Joint Commission
- Submitted electronically by the laboratory to The Joint Commission

**Note 2:** For the purpose of this requirement, falsification is defined as the fabrication, in whole or in part, and through commission or omission, of any information provided by an applicant or accredited laboratory to The Joint Commission. This includes redrafting, reformatting, or deleting document content. However, the laboratory may submit supporting material that explains the original information submitted to The Joint Commission. These additional materials must be properly identified, dated, and accompanied by the original documents.

**APR.01.03.01**

The laboratory reports any changes in the information provided in the application for accreditation and any changes made between surveys.

**Element of Performance for APR.01.03.01**

1. The laboratory notifies The Joint Commission in writing within 30 days of a change in ownership, control, location, capacity, or services offered.

**Note:** When the laboratory changes ownership, control, location, capacity, or services offered, it may be necessary for The Joint Commission to survey the laboratory again. If the laboratory does not provide written notification to The Joint Commission within 30 days of these changes, the laboratory could lose its accreditation.

**APR.02.01.01**

The laboratory permits the performance of a survey at The Joint Commission’s discretion.

**Element of Performance for APR.02.01.01**

1. The laboratory permits the performance of a survey at The Joint Commission’s discretion.
APR.03.01.01

The laboratory fulfills requirements for Focused Standards Assessment.

**Rationale for APR.03.01.01**

The Focused Standards Assessment (FSA) helps laboratories incorporate The Joint Commission standards into routine daily operations. When laboratories use the FSA tool to self-assess, monitor, and improve services, their patients are more likely to receive safe, high-quality care on a constant basis.

**Elements of Performance for APR.03.01.01**

1. ☑️ The laboratory, at 12 months after its full biennial survey, updates and submits to The Joint Commission the full Focused Standards Assessment (FSA) and its Plan of Action on any recommendations cited. (Refer also to the “Focused Standards Assessment [FSA]” section in “The Accreditation Process” [ACC] chapter.)

   **Note 1:** *For laboratories that select Options 1, 2, or 3, the requirement to transmit the FSA and its Plan of Action to The Joint Commission may not apply in part or in whole.*

   **Note 2:** *Neither the full FSA nor FSA Options 1, 2, or 3 are due in the year of the laboratory’s biennial survey.*

3. ☑️ The laboratory exercising Option 1, 2, or 3 for the Focused Standards Assessment (FSA) attests at 12 months after its full biennial survey that the organization has decided not to participate in the submission of the full FSA.

   **Note:** *Neither the full FSA nor FSA Options 1, 2, or 3 are due in the year of the organization’s biennial survey.*

4. ☑️ The laboratory exercising Option 1 for the Focused Standards Assessment (FSA) completes an FSA and Plan of Action.

   **Note:** *The laboratory does not submit this information to The Joint Commission.*

6. ☑️ The laboratory exercising Option 2 for the Focused Standards Assessment agrees to undergo a limited survey and then submit a Plan of Action for recommendations cited as a result of the survey.

7. The laboratory exercising Option 3 for the Focused Standards Assessment agrees to undergo a limited survey.

   **Note:** *The laboratory does not receive a written report after the survey.*
APR.05.01.01
The laboratory allows The Joint Commission to review the results of external evaluations from publicly recognized bodies.

Rationale for APR.05.01.01
In order to conduct a meaningful accreditation survey, The Joint Commission collects information on many aspects of the laboratory’s performance. External bodies other than The Joint Commission evaluate areas related to safety and quality. These evaluations complement accreditation reviews but may have a different focus or emphasis. These evaluations may contain information The Joint Commission needs to make accreditation decisions.

Element of Performance for APR.05.01.01
1. When requested, the laboratory provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.

APR.06.01.01
Applicants and accredited laboratories do not use Joint Commission employees to provide accreditation-related consulting services.

Element of Performance for APR.06.01.01
1. The laboratory does not use Joint Commission employees to provide any accreditation-related consulting services.

Note: Consulting services include, but are not limited to, the following:
- Helping the laboratory to meet Joint Commission standards
- Helping the laboratory to complete its Focused Standards Assessment (FSA)
- Assisting the laboratory in remedying areas identified in its FSA as needing improvement
- Conducting mock surveys

APR.07.01.01
The laboratory accepts the presence of Joint Commission surveyor management staff or a Board of Commissioners member in the role of observer of an on-site survey.

Element of Performance for APR.07.01.01
1. The laboratory allows Joint Commission surveyor management staff or a member of the Board of Commissioners to observe the on-site survey.
Note 1: The observer will not participate in the on-site survey process, including the scoring of standards compliance. Surveyor management staff will only participate in the survey process if he or she feels it is necessary to bring any potential findings or observations to the attention of the surveyor and the laboratory.

Note 2: The laboratory will not incur any additional survey fees because an observer(s) is present.

APR.08.01.01
The laboratory accurately represents its accreditation status and the programs and services to which Joint Commission accreditation applies.

Elements of Performance for APR.08.01.01
1. The laboratory’s advertising accurately reflects the scope of programs and services that are accredited by The Joint Commission.
2. The laboratory does not engage in any false or misleading advertising about its accreditation award.

APR.09.01.01
The laboratory notifies the public it serves about how to contact laboratory management and The Joint Commission to report concerns about patient safety and quality of care.

Note: Methods of notice may include, but are not limited to, distribution of information about The Joint Commission, including contact information in published materials such as brochures and/or posting this information on the laboratory’s website.

Elements of Performance for APR.09.01.01
1. The laboratory informs the public it serves about how to contact its management to report concerns about patient safety and quality of care.
2. The laboratory informs the public it serves about how to contact The Joint Commission to report concerns about patient safety and quality of care.

APR.09.02.01
Any individual who provides laboratory services can report concerns about safety or the quality of care to The Joint Commission without retaliatory action from the laboratory.
Rationale for APR.09.02.01
Any individual who provides laboratory services should be free to raise concerns to The Joint Commission when the laboratory has not adequately prevented or corrected problems that can have or have had a serious adverse impact on patients. To support this culture of safety, the laboratory must communicate to staff that such reporting is permitted. Further, the laboratory must make it clear to staff that no formal disciplinary actions (for example, demotions, reassignments, or change in working conditions or hours) or informal punitive actions (for example, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to The Joint Commission.

Elements of Performance for APR.09.02.01

1. The laboratory educates its staff and other individuals who provide laboratory services that concerns about the safety or quality of services provided in the laboratory may be reported to The Joint Commission.

2. The laboratory informs its staff that it will take no disciplinary or punitive action because an employee or other individual who provides laboratory services reports safety or quality-of-care concerns to The Joint Commission.

3. The laboratory takes no disciplinary or punitive action against employees or other individuals who provide laboratory services when they report safety or quality-of-care concerns to The Joint Commission.

APR.09.03.01
The laboratory is truthful and accurate when describing information in its Quality Report to the public.

Element of Performance for APR.09.03.01

1. The laboratory adheres to The Joint Commission’s published guidelines for how it describes information in its Quality Report.

APR.09.04.01
The laboratory provides care, treatment, services, and an environment that pose no risk of an “Immediate Threat to Health or Safety,” also known as “Immediate Threat to Life” or ITL situation.
Element of Performance for APR.09.04.01

1. The laboratory provides care, treatment, services, and an environment that pose no risk of an “Immediate Threat to Health or Safety,” also known as “Immediate Threat to Life” or ITL situation.

APR.10.03.01

The laboratory complies with The Joint Commission’s requirements addressing unsuccessful proficiency testing.

Note: Unsuccessful proficiency testing is defined as a failure to achieve satisfactory performance for two consecutive or two out of three consecutive testing events. The following are considered unsatisfactory proficiency testing events:

- Failure to attain a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (Rh) typing and compatibility testing
- Failure to attain a score of 100% for ABO group and D (Rh) typing and compatibility testing
- Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider
- Omission of results on the proficiency testing form
- Failure to participate in a proficiency testing event

Elements of Performance for APR.10.03.01

1. If notified by The Joint Commission of an unsuccessful proficiency testing status, the laboratory submits a plan of action within 10 calendar days of notification.

The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs:

2. The laboratory has failed to submit a written Plan of Action after two requests from The Joint Commission.

   Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

3. The Plan of Action has not been found acceptable by The Joint Commission after three opportunities to provide an acceptable plan.
Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

4. The laboratory fails to achieve satisfactory performance on one of the next two consecutive proficiency testing events.

Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

5. The nature, scope, severity, and duration of the underlying issue warrants a cease in testing, such as nonsequential, but repeated, unsuccessful proficiency testing events.

Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.
Prompts to Assess Your Compliance

**Please note:** Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

When is the Intracycle Monitoring process due? Will you complete a full Focused Standard Assessment (FSA) or one of the three options? (APR.03.01.01)

**TIP:** Start the annual evaluation early, so the report is thorough and thoughtful.

Who is responsible for updating and maintaining the electronic application (E-App) for survey? When was the E-App last updated? (APR.01.01.01, APR.01.02.01, APR.01.03.01)

How were staff educated and informed about reporting concerns to The Joint Commission? (APR.09.01.01)

**TIP:** Confirm that the laboratory’s policy for unsuccessful proficiency testing results meets The Joint Commission requirements.
Written Documentation Checklist
This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

### Accreditation Participation Requirements (APR)

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
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<tr>
<td></td>
<td>APR.01.03.01, EP 1</td>
<td>The laboratory notifies The Joint Commission in writing within 30 days of a change in ownership, control, location, capacity, or services offered. <strong>Note:</strong> When the laboratory changes ownership, control, location, capacity, or services offered, it may be necessary for The Joint Commission to survey the laboratory again. If the laboratory does not provide written notification to The Joint Commission within 30 days of these changes, the laboratory could lose its accreditation.</td>
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<td>APR.03.01.01, EP 1</td>
<td>The laboratory, at 12 months after its full biennial survey, updates and submits to The Joint Commission the full Focused Standards Assessment (FSA) and its Plan of Action on any recommendations cited. (Refer also to the “Focused Standards Assessment [FSA]” Options section in “The Accreditation Process” [ACC] chapter.) <strong>Note 1:</strong> For laboratories that select Options 1, 2, or 3, the requirement to transmit the FSA and its Plan of Action to The Joint Commission may not apply in part or in whole. <strong>Note 2:</strong> Neither the full FSA nor FSA Options 1, 2, or 3 are due in the year of the laboratory’s biennial survey.</td>
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<td>APR.03.01.01, EP 3</td>
<td>The laboratory exercising Option 1, 2, or 3 for the Focused Standards Assessment (FSA) attests at 12 months after its full biennial survey that the organization has decided not to participate in the submission of the full FSA. <strong>Note:</strong> Neither the full FSA nor FSA Options 1, 2, or 3 are due in the year of the organization’s biennial survey.</td>
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<td>APR.03.01.01, EP 4</td>
<td>The laboratory exercising Option 1 for the Focused Standards Assessment (FSA) completes an FSA and Plan of Action. <strong>Note:</strong> The laboratory does not submit this information to The Joint Commission.</td>
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<tr>
<td>APR.03.01.01, EP 6</td>
<td>The laboratory exercising Option 2 for the Focused Standards Assessment agrees to undergo a limited survey and then submit a Plan of Action for recommendations cited as a result of the survey.</td>
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<td>APR.05.01.01, EP 1</td>
<td>When requested, the laboratory provides The Joint Commission with all official records and reports of licensing, examining, reviewing, or planning bodies.</td>
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<td>APR.10.03.01, EP 1</td>
<td>If notified by The Joint Commission of an unsuccessful proficiency testing status, the laboratory submits a plan of action within 10 calendar days of notification.</td>
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# Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Document and Process Control (DC)

Overview
Labs provide complex services that are essential to diagnosis and treatment of patients. In order to provide timely and accurate services, labs strive to minimize errors that may occur throughout the continuum of testing, from preanalytical through postanalytical phases. Errors within the preanalytical phase of testing often result from system breakdowns, such as inaccurate lab orders, misidentified patients, mislabeled specimens, or incorrect specimen containers. Coordination and integration of the work of the many individuals involved in collecting and handling specimens is important. Errors that may occur in the postanalytical phase of testing include unavailable results or incomplete results. Controlling both pre- and postanalytical testing factors can provide for accurate results and improve patient safety.

Numerous resources are available to provide detailed technical guidance, such as resources from the Clinical and Laboratory Standards Institute (CLSI). Labs are encouraged to take advantage of the information that is available from these resources.

About This Chapter
This chapter contains a comprehensive set of requirements for the preanalytical and postanalytical phases of testing. The requirements address specimen collection, lab test orders, specimen identification, test procedures, testing staff identification, test reporting, and record retention. Standards describe the procedures for specimen collection, ordering of laboratory tests, and step-by-step description of the performance of each test. The chapter also contains requirements that guide the completion, authentication, retention, and retrieval of laboratory reports.
Chapter Outline

I. Preanalytic Phase of Laboratory Testing
   A. Procedures for Collecting Specimens (DC.01.01.01)
   B. Request for Laboratory Tests (DC.01.02.01, DC.01.02.03)
   C. Specimen Identification (DC.01.03.01)

II. Postanalytic Phase of Laboratory Testing
   A. Testing Procedures (DC.02.01.01, DC.02.01.03, DC.02.01.05, DC.02.01.07)
   B. Testing Staff Identification (DC.02.02.01)
   C. Reporting (DC.02.03.01, DC.02.03.03)
   D. Records Retention (DC.02.04.01)

III. Hand-off Communications (DC.03.01.01)
Standards, Rationales, and Elements of Performance

Standard DC.01.01.01
The laboratory establishes procedures for collecting specimens.

Rationale for DC.01.01.01
A specimen that is properly timed, collected, identified, preserved, stored, received, and processed is the first step toward achieving an accurate result.

Elements of Performance for DC.01.01.01

1. The laboratory has written procedures for collecting specimens that address the following:
   - Patient identification
   - Patient preparation
   - Specimen collection
   - Precautions for specimen collection, including preventing cross-contamination of primary samples and sample portions shared between testing centers
   - Specimen labeling, including date, and when pertinent to the test being ordered, time of specimen collection and source of specimen, and other labeling information required by laboratory policy
   - Specimen receipt, processing (including maintaining cell and organism viability), storage, preservation, and transport
   - Specimen rejection criteria
   - Collection of reference laboratory specimens

   (See also QSA.15.01.01, EP 4)

   **Note**: The laboratory may use a reference laboratory’s procedures—they need not be rewritten.

2. Current specimen collection procedures are made available to laboratory staff, nonlaboratory staff, and external providers who collect specimens for laboratory testing.

   **Note**: Electronic specimen collection procedure manuals may be used if they are accessible to staff.

3. Staff follow the laboratory’s procedures for specimen collection.
Standard DC.01.02.01
The laboratory performs testing based on written (paper or electronic) laboratory test orders.

Elements of Performance for DC.01.02.01

1. ☐ The laboratory has written procedures for ordering tests.

2. Individuals who order laboratory tests or receive laboratory test results are authorized to do so in accordance with law and regulation.

3. ☐ Laboratory test orders are made in writing (paper or electronic).
   
   Note: The test order may be located in the clinical record.

4. Orders for laboratory tests are legible.

5. Laboratory test orders are complete and include the following:
   - Patient’s first and last name
   - Patient’s sex
   - Patient’s age or date of birth
   - Contact information of the authorized person requesting the test, and if different, the individual responsible for using the test results, in order to report routine and critical test values
   - Name of the test(s) ordered
   - Any special handling required
   - Date and, when pertinent to the test being ordered, time the specimen was collected
   - Date and time the specimen arrived at the laboratory
   - The specimen source, when pertinent to the test being ordered
   - Additional information required by the laboratory to support accurate test interpretation and reporting of results, such as race, ethnicity, or family history

6. The laboratory has a policy defining the criteria for specimen and requisition acceptability which addresses the processes to follow to obtain missing test order information prior to processing specimens or reporting patient results.

7. ☐ If the laboratory permits verbal orders for laboratory testing, the laboratory requests written (paper or electronic) authorization within 30 days and retains the written authorization, or documentation of its attempts to obtain written authorization, in accordance with law and regulation.
8. Laboratory test orders for interpretation of Pap tests include the following:
   - The date of the woman’s last menstrual period
   - Information on previous abnormal reports, treatments, or biopsies

9. Before taking action on a verbal order or verbal report of a test result, staff uses a record and “read back” process to verify the information.

10. Laboratory test orders for genetic linkage analysis studies include a pedigree.

11. Clinical standing orders, order sets, and protocols are dated, timed, authenticated, and included in the patient’s clinical record.

**Standard DC.01.02.03**
The laboratory has written procedures for ordering maternal serum marker prenatal screening tests.

**Elements of Performance for DC.01.02.03**
Laboratory test orders for maternal serum marker prenatal screening are complete and include the following information:

1. Maternal date of birth.
3. Date of last menstrual period or ultrasound dating of gestation.
5. Confirmation or denial of the patient’s history of insulin dependent diabetes.
7. Documentation of initial or repeat screening test.

**Standard DC.01.03.01**
The laboratory has a system for maintaining the integrity of, uniquely identifying, and retrieving records for each specimen.

**Elements of Performance for DC.01.03.01**
1. The laboratory has a system for uniquely identifying each specimen collected or received by the laboratory.
Note: This is accomplished by providing each specimen with an individual accession number or any other method that identifies each specimen in a unique way.

2. The unique identification for each specimen has the following characteristics:
   - It is included in the labeling of each specimen.
   - It is an identifier in the analytical phases of patient testing.
   - It is part of the laboratory record for the specimen.

3. The laboratory maintains specimen identity throughout all testing phases.

4. The laboratory is able to retrieve specimens it collects, receives, or tests by date, patient name, or unique identifier within a regular working day.

   Note: This information does not need to be kept in one place or on a single log in the laboratory. A combination of work logs and test reports can satisfy this requirement.

5. The laboratory is able to retrieve data on the test order or test report by date, patient name, or unique identifier within a regular working day. (See also DC.02.04.01, EPs 8 and 9)

   Note: This information does not need to be kept in one place or on a single log in the laboratory. A combination of work logs and test reports can satisfy this requirement.

Standard DC.02.01.01
The laboratory has procedures for each laboratory test.

Rationale for DC.02.01.01
Written procedures play an important role in patient safety. They describe the work standards of the laboratory and the steps to be followed when conducting laboratory tests. When procedures are comprehensive and followed by staff, the laboratory can be confident that it will produce and report accurate test results.

Elements of Performance for DC.02.01.01

1. Written laboratory procedures for each test meet the following requirements:
   - They contain a complete description of the test.
   - They include detailed instructions for performing the test.
   - They adhere to manufacturers’ instructions (preanalytical, analytical, and postanalytical phases of testing).
   - They include the date of implementation.
   - They reflect the laboratory’s current practice.
   - They are readily available to staff performing the testing.
Note 1: Test procedures include, but are not limited to, the following:

- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Criteria for confirmatory testing
- Pertinent literature references

Note 2: An exception to including manufacturers’ instructions is allowed when the laboratory establishes the performance specifications for test procedures with modifications to the manufacturer’s instructions.

(See also LD.04.05.09, EPs 1, 2, and 10)

2. Discontinued procedures are retained for at least two years and include the implementation and discontinuation dates.

3. If manufacturers’ manuals or package inserts are used as procedures, they are modified to include specific laboratory operational policies.

Note: These may include detailed quality control protocols, calibration protocols, and other institution-specific procedures regarding the test or instrument.

4. Staff follow the laboratory’s procedures for each test.

Standard DC.02.01.03

The laboratory proactively plans for interruptions in services.

Element of Performance for DC.02.01.03

1. The laboratory has written policies and procedures that address the course of action to follow when a test system becomes unavailable (for example, downtime procedures).
Standard DC.02.01.05

The laboratory provides accurate flow cytometry results.

Elements of Performance for DC.02.01.05

1. The laboratory has written quality control and test procedures for lymphocyte subset and CD34+ enumeration by flow cytometry.

2. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Monitors of flow cytometer instrument performance. *(See also EC.02.04.05, EPs 1–5)*

3. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Quality control requirements for monitoring the analytic process. *(See also QSA.02.10.03, EPs 1–4)*

4. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Selection of anticoagulant for specimen collection.

5. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Specimen acceptability criteria for testing.

6. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Protocol for sample preparation and staining.

7. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Minimum acceptable specimen viability criteria.

8. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure-specific issues including the following: Selection of reagents based on the clinical problem presented for investigation.
9. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure specific issues including the following: Validation of the gating parameters and techniques used to select the cell population of interest.

   **Note:** Sequential gating techniques are used to define CD34+ stem cell population.

10. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure specific issues including the following: Determination of placement of markers to distinguish fluorescence negative from fluorescence positive cell populations.

11. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure specific issues including the following: Minimum number of events required for rare event analyses (for example, CD34+ stem cell).

12. The laboratory’s written quality control and test procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry address procedure specific issues including the following: Reporting requirements, including correction of lymphocyte subset analysis for gate purity when greater than five percent of non-lymphocyte events are included in the gate.

13. Staff follow the procedures for blood lymphocyte subset and CD34+ enumeration by flow cytometry.

**Standard DC.02.01.07**

The laboratory provides accurate flow cytometry results of neoplastic hematolymphoid cells.

**Elements of Performance for DC.02.01.07**

1. The laboratory has written quality control and test procedures for flow cytometry analysis of neoplastic hematolymphoid cells.

2. The laboratory’s written quality control and test procedures for flow cytometry analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: Processing of neoplastic specimens, including policies for processing irreplaceable neoplastic source specimens that have exceeded the laboratory-defined time period for acceptable specimen age.
3. The laboratory’s written quality control and test procedures for flow cytometric analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: The preferred anticoagulant for the specimen sample type.

4. The laboratory’s written quality control and test procedures for flow cytometric analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: Determination of sample viability.

5. The laboratory’s written quality control and test procedures for flow cytometric analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: Monoclonal antibody panels, including the number of reagents required to provide a complete characterization of normal and neoplastic cells.

6. The laboratory’s written quality control and test procedures for flow cytometric analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: Adjustment of cell concentrations in specimens with abnormal cell counts to provide optimal antibody staining.

7. The laboratory’s written quality control and test procedures for flow cytometric analysis of neoplastic hematolymphoid cells address procedure-specific issues including the following: Establishment of methods to provide intrinsic immunoglobulin staining of abnormal cells.

8. The laboratory follows its quality control and test procedures for flow cytometry analysis of neoplastic hematolymphoid cells.

**Standard DC.02.02.01**

The laboratory identifies the individual(s) responsible for performing and reporting laboratory procedures.

**Elements of Performance for DC.02.02.01**

1. The laboratory is able to identify the individual(s) performing and reporting the laboratory procedure including the preanalytical, analytical, and postanalytical phases of testing.

   **Note:** The individual(s) performing and reporting the laboratory procedure does not need to be identified in the report filed in the patient’s clinical record. However, reports that require specific interpretation, such as surgical pathology reports, must identify the individual making the interpretation.
2. When the laboratory uses initials or other unique identifiers to identify the individual(s) performing and reporting the laboratory procedure, a written list of names that includes the initials or other unique identifiers for the staff is maintained.

**Standard DC.02.03.01**

The laboratory report is complete and is in the patient’s clinical record.

**Elements of Performance for DC.02.03.01**

1. The laboratory report is maintained in the patient’s clinical record.

The laboratory report includes the following information:

2. The name and address of the laboratory performing the test.

3. The patient’s first and last name.

4. The patient identifier, which cannot be the patient’s room number or physical location.

5. The sex of the patient.

6. The age or date of birth of the patient.

7. The specimen collection date (and time, when pertinent to the test performed).

8. The specimen source, when pertinent to the test performed.

9. The condition of unsatisfactory specimens, if applicable.

10. The results of examinations and tests performed.

11. The authentication of interpretive reports, such as surgical pathology reports.

12. The date and time the test results were generated as a final report. The date and time cannot be changed on copies of the report that are made at a later date. (*See also* DC.02.03.03, EP 1)

13. The result units (that is, concentration or activity) for quantitative analytes.
14. Test reports for nonwaived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (For waived testing, see also WT.05.01.01, EP 3)

**Note 1:** This requirement also applies to reference laboratory reports.

**Note 2:** If the reference intervals (normal values) are not documented on the same page as and adjacent to the laboratory result, there must be a notation directing the reader to their location.

15. The laboratory does not revise results or information related to the interpretation of results in a reference laboratory’s report.

16. The individual identified by the electronic signature, written signature or initials, rubber-stamp signature, or computer key used for authentication is the only individual who uses it.

17. For interpretive reports, the qualified individual providing the interpretation authenticates the results.

**Note:** Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key.

**Standard DC.02.03.03**

The laboratory maternal serum marker prenatal screening report provides the information necessary for accurate interpretation.

**Elements of Performance for DC.02.03.03**

1. The laboratory maternal serum marker prenatal screening report is complete and in the patient’s clinical record. (For more information, refer to Standard DC.02.03.01)

The maternal serum marker prenatal screening report includes the following information:


3. The maternal serum marker prenatal screening report includes the information: Maternal weight.

4. The maternal serum marker prenatal screening report includes the information: Date of last menstrual period or ultrasound dating of gestation.

5. The maternal serum marker prenatal screening report includes the information: Maternal race.

6. The maternal serum marker prenatal screening report includes the information: Confirmation or denial of history of insulin dependent diabetes of the patient.

7. The maternal serum marker prenatal screening report includes the information: Documentation of initial or repeat screening test.

8. The maternal serum marker prenatal screening report includes the information: Family history of neural tube defect.

**Standard DC.02.04.01**

The laboratory retains records as required by law and regulation.

**Elements of Performance for DC.02.04.01**

1. The laboratory retains quality control records, including test system performance specifications and quality system assessments, for at least two years, or longer if required by law and regulation.

2. The laboratory retains immunohematology records, including blood, blood component, and transfusion records, for at least 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date.

   **Note:** When there is no expiration date for the blood or blood component, immunohematology records are retained indefinitely.

3. The laboratory retains histocompatibility records for at least five years, or longer if required by law and regulation.

4. The laboratory retains test orders for at least two years, or longer if required by law and regulation.

   **Note:** This includes the patient’s clinical record, if it is used as the test order.

5. The testing laboratory retains instrument printouts for at least two years, or longer if required by law and regulation.
**Note:** Retained records may be paper or electronic. Electronic systems must be able to retrieve all information printed on the original hard copy generated at the time of testing in order to be considered satisfactory for compliance.

6. The testing laboratory retains an original test report or an exact copy, including preliminary, final, corrected, and reference laboratory reports, for the following periods:
   - At least 5 years for histocompatibility reports
   - At least 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date for immunohematology reports
   - At least 10 years for histopathology and cytology reports
   - At least 2 years for all other reports

**Note 1:** The exact copy includes the name and address of the laboratory performing the test. The copy may be on paper or maintained in a computer system, microfilm, or microfiche record. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing individual identifiers, the copy includes the signature or individual identifiers.

**Note 2:** The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially ordered the test. The referring laboratory must retain or be able to produce an exact copy of each testing laboratory’s test report.

**Note 3:** For immunohematology: When there is no expiration date, records shall be retained indefinitely.

7. When an amended report of a patient result is issued for any reason, the laboratory report clearly identifies the result as a change from the original report.

8. For all other laboratory records, the laboratory complies with law and regulation for record retention. *(See also DC.01.03.01, EP 5)*

9. The laboratory is able to retrieve reports in a timely manner to support patient care and other activities. *(See also DC.01.03.01, EP 5)*

10. The laboratory maintains records, slides, blocks, and tissues and makes arrangements for their availability for the time frames required by law and regulation in the event that the laboratory ceases to operate.
Standard  DC.03.01.01
The laboratory implements a standardized approach to hand-off communications.

Element of Performance for DC.03.01.01

1. The laboratory’s process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information.

   Note: Such information may include the patient’s condition, care, treatment, medications, services, and any recent or anticipated changes to any of these.
Prompt to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

What items are addressed in the laboratory’s specimen collection procedures? Can staff locate the specimen collection procedures they require to perform their job responsibilities? (DC.01.01.01)

Who is authorized to order and receive laboratory test results? (DC.01.02.01, DC.01.02.03)

TIP: Verify that the laboratory test orders include complete information required to support laboratory test interpretation and reporting. Review additional information required for specific test orders such as pap technique, genetic testing, prenatal screening tests, therapeutic drug monitoring, etc.

How does the laboratory follow up with verbal orders, if allowed? (DC.01.02.01)

How does the laboratory maintain the integrity and accurate patient identification of each specimen throughout the testing process (preanalytical, analytical, and post-analytical)? (DC.01.03.01)
**TIP:** Conduct orientation of proper specimen collection, labeling, and transport procedures to all staff involved with the laboratory specimen handling. Create a list of required data for specimen labeling of each laboratory test order and make the list available at the accessioning area.

Can staff locate procedures for each test the laboratory offers? (DC.01.02.01)

**TIP:** Create a log (paper or electronic) that lists all laboratory tests and specify the location where each laboratory procedure can be found.

How does the laboratory continue operation during power interruption? (DC.02.01.03)

**TIP:** Review laboratory test results when such testing is completed while equipment is down and when the test system becomes available.

What information is included in both the laboratory test report AND the patient’s clinical record? Does the laboratory report include ALL required information pertinent to the test performed? (DC.02.03.01)
**TIP:** Review results from reference laboratory and frozen section reports to make sure all required information is included in each test report.

**TIP:** Review The Joint Commission’s FAQ for Laboratory Report Requirements in the Medical Record.

How does the laboratory maintain accurate transfer information when transitioning between paper and electronic records? (DC.01.02.01)

What are the established retention times for laboratory records, reports, and specimens? (DC.02.04.01)

**TIP:** Review Appendix A: Retention Times for Records, Reports, and Specimens in this manual.
**Written Documentation Checklist**

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

### Document and Process Control (DC)

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- Precautions for specimen collection, including preventing cross-contamination of primary samples and sample portions shared between testing centers  
- Specimen labeling, including the date, and when pertinent to the test being ordered, time of specimen collection and source of specimen, and other labeling information required by laboratory policy  
- Specimen receipt, processing (including maintaining cell and organism viability), storage, preservation, and transport  
- Specimen rejection criteria  
- Collection of reference laboratory specimens *(See also QSA.15.01.01, EP 4)*  
*(Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten.)* |                     |
|   | DC.01.02.01, EP 1 | The laboratory has written procedures for ordering tests. |                     |
|   | DC.01.02.01, EP 3 | Laboratory test orders are made in writing (paper or electronic). *(Note: The test order may be located in the clinical record.)* |                     |
|   | DC.01.02.01, EP 7 | If the laboratory permits verbal orders for laboratory testing, the laboratory requests written (paper or electronic) authorization within 30 days and retains the written authorization, or documentation of its attempts to obtain written authorization, in accordance with law and regulation. |                     |
|   | DC.01.02.01, EP 11 | Clinical standing orders, order sets, and protocols are dated, timed, authenticated, and included in the patient’s clinical record. |                     |
| DC.01.03.01, EP 2 | The unique identification for each specimen has the following characteristics:
- It is included in the labeling of each specimen.
- It is an identifier in the analytical phases of patient testing.
- It is part of the laboratory record for the specimen. |
| DC.02.01.01, EP 1 | Written laboratory procedures for each test meet the following requirements:
- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers’ instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory’s current practice.
- They are readily available to staff performing the testing.  
  **Note 1:** Test procedures include, but are not limited to, the following:
  - A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
  - Microscopic examination, including the detection of inadequately prepared slides
  - Result entry in the patient clinical record
  - Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
  - Control and calibration procedures
  - Reference intervals (normal values)
  - Reportable range
  - Special precautions
  - Limitations in the test methodology, including interfering factors
  - Criteria for confirmatory testing
  - Pertinent literature references  
  **Note 2:** An exception to including manufacturers’ instructions is allowed when the laboratory establishes the performance specifications for test procedures with modifications to the manufacturer’s instructions. (See also LD.04.05.09, EPs 1, 2, and 10.) |
| DC.02.01.01, EP 2 | Discontinued procedures are retained for at least two years and include the implementation and discontinuation dates. |
| DC.02.01.03, EP 1 | The laboratory has written policies and procedures that address the course of action to follow when a test system becomes unavailable (for example, downtime procedures). |
| DC.02.01.05, EP 1 | The laboratory has written quality control and test procedures for lymphocyte subset and CD34+ enumeration by flow cytometry. |
| DC.02.01.07, EP 1 | The laboratory has written quality control and test procedures for flow cytometry analysis of neoplastic hematolymphoid cells. |
| DC.02.02.01, EP 2 | When the laboratory uses initials or other unique identifiers to identify the individual(s) performing and reporting the laboratory procedure, a written list of names that includes the initials or other unique identifiers for the staff is maintained. |
# Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Environment of Care (EC)

Overview
The goal of this chapter is to promote a safe, functional, and supportive environment within the laboratory so that quality and safety are preserved. The environment of care is made up of three basic elements:

- The building or space, including how it is arranged and special features that protect patients, visitors, and staff
- Equipment used to support laboratory services or to safely operate the building or space
- People, including those who work within the laboratory, patients, and anyone else who enters the environment, all of whom have a role in minimizing risks

This chapter stresses the importance of managing risks in the environment of care, which are different from the risks associated with laboratory services. Any laboratory, regardless of its size or location, faces risks in the environment, including those associated with safety and security, fire, hazardous materials and waste, laboratory equipment, and utility systems. When staff are educated about the elements of a safe environment, they are more likely to follow processes for identifying, reporting, and taking action on environmental risks.

If the laboratory is part of an accredited organization that meets the requirements of this chapter, the laboratory is not required to create a separate plan(s) for managing the five categories of risk (safety and security, hazardous materials and waste, fire safety, equipment, and utility systems). The laboratory can rely on the accredited organization’s plan(s) and management activities. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting all requirements in this chapter.

About This Chapter
The standards are organized around the concepts of planning, implementation, and evaluation of results. The chapter calls for written plans for managing risks in each of these areas. Laboratories may choose to address all required components of the environment in a single management plan or in several different plans. If a laboratory
has multiple sites, it may have separate management plans for each of its locations, or it may choose to have one comprehensive set of plans. In any case, the laboratory must address specific risks and the unique conditions at each of its sites.

The standards address the need to identify someone to manage environmental risks as well as to intervene when situations threaten people or property; both responsibilities may be assigned to one person. It is important to remember that the standards in this chapter do not prescribe a particular structure (such as a safety committee) or individual (such as one employee hired to be a safety officer) for managing the environment, nor do they prescribe how required planning activities are conducted.

Important aspects of the environment addressed in the standards include the following:

- **Safety and security.** This section addresses risks in the physical environment, access to security-sensitive areas, product recalls, and smoking.
- **Hazardous materials and waste.** This section addresses risks associated with hazardous chemicals, radioactive materials, hazardous energy sources, hazardous medications, and hazardous gases and vapors.
- **Fire safety.** This section addresses risks from fire, smoke, and other products of combustion; fire response plans; fire drills; management of fire detection, alarm, and suppression equipment and systems; and measures to implement during construction or when the *Life Safety Code®* cannot be met.
- **Laboratory equipment:** This section addresses selection, testing, and maintenance of laboratory equipment, and contingencies when equipment fails.
- **Utilities.** This section addresses inspection and testing of operating components, control of airborne contaminants, and management of disruptions.

**Note:** Emergency management standards are located in a separate chapter.

**Other Issues for Consideration**

1. The laboratory that provides services in space it does not own (for example, in leased or complimentary space) may want to communicate with the property owner about maintenance expectations for building equipment and features not under its control. For example, a laboratory may need access to the maintenance documents. This laboratory and the property owner may want to discuss any building or equipment problems that could adversely affect the safety or health of patients, staff, and other people coming to the laboratory, as well as the property owner’s plan to resolve such issues.

*Life Safety Code®* is a registered trademark of the National Fire Protection Association, Quincy, MA.
2. A number of elements of performance describe time frames for completing certain tasks or functions. The Joint Commission recognizes that it will not always be possible to meet the exact time frames cited in the requirements. For evaluation purposes, therefore, the following intervals are acceptable:

- Every 36 months/every 3 years = 36 months from the last event, plus or minus 45 days
- Annually/every 12 months/once a year/every year = 1 year from the last event, plus or minus 30 days
- Every 6 months = 6 months from the last event, plus or minus 20 days
- Quarterly/every quarter = every three months, plus or minus 10 days
- Monthly/30-day intervals/every month = 12 times a year, once per calendar month
- Every week = once per calendar week
Chapter Outline

I. Plan (EC.01.01.01)

II. Implement
   A. Safety and Security (EC.02.01.01, EC.02.01.03)
   B. Hazardous Materials and Waste (EC.02.02.01)
   C. Fire Safety (EC.02.03.01, EC.02.03.03, EC.02.03.05)
   D. Laboratory Equipment (EC.02.04.01, EC.02.04.03, EC.02.04.05)
   E. Utilities (EC.02.05.01, EC.02.05.03, EC.02.05.05, EC.02.05.07)
   F. Other Physical Environment Requirements (EC.02.06.01, EC.02.06.05)

III. Staff Demonstrate Competence (EC.03.01.01)

IV. Monitor and Improve (EC.04.01.01, EC.04.01.03, EC.04.01.05)
Standards, Rationales, and Elements of Performance

**Standard EC.01.01.01**
The laboratory plans activities that minimize risks in the environment of care.

*Note:* One or more persons can be assigned to manage risks associated with the management plans described in this standard.

**Rationale for EC.01.01.01**
Risks are inherent in the environment because of the types of care provided and the equipment and materials that are necessary to provide that care. The best way to manage these risks is through a systematic approach that involves the proactive evaluation of the harm that could occur. By identifying one or more individuals to coordinate and manage risk assessment and reduction activities—and to intervene when conditions immediately threaten life and health—laboratories can be more confident that they have minimized the potential for harm. Risks in the environment include safety and security for people, equipment, and other material; the handling of hazardous materials and waste; the potential for fire; the use of laboratory equipment; and utility systems.

Written management plans help the laboratory manage risks. These plans are not the same as operational plans, but they do provide a framework for managing the environment of care. These plans should also address the scope and objectives of risk assessment and management, describe the responsibilities of individuals or groups, and give time frames for specific activities identified in the plan.

*Note:* It is not necessary to have a separate plan for each of the areas identified in the standard; they may all be contained in a single document.

**Elements of Performance for EC.01.01.01**
1. Laboratory leaders identify an individual(s) to manage risk, coordinate risk reduction activities in the environment of care, collect information on deficiencies, and disseminate summaries of actions and results.

*Note 1:* This information is disseminated to individuals with responsibility for the issues being addressed.

*Note 2:* Deficiencies include injuries, problems, or use errors.
4. The laboratory has a written plan for providing a safe environment for everyone who enters the laboratory’s facilities.

5. The laboratory has a written plan for providing a secure environment for everyone who enters the laboratory’s facilities.

The laboratory has a written plan for managing the following:

6. Hazardous materials and waste.

7. Fire safety.

8. Laboratory equipment.

9. Utility systems.

**Standard EC.02.01.01**
The organization manages safety and security risks.

**Rationale for EC.02.01.01**
Safety and security risks are present in most health care environments. These risks affect all individuals in the organization—patients, visitors, and those who work in the laboratory. It is important to identify these risks in advance so that the laboratory can prevent or effectively respond to incidents. In some laboratories, safety and security are treated as a single function, although in others they are treated as separate functions.

Safety risks may arise from the structure of the physical environment or the performance of everyday tasks, or be related to situations beyond the laboratory’s control, such as the weather. Safety incidents are most often accidental. On the other hand, security incidents are often intentional. Security protects individuals and property against harm or loss. Examples of security risks include workplace violence, theft, and unrestricted access to medications. Security incidents are caused by individuals from either outside or inside the laboratory.

**Elements of Performance for EC.02.01.01**

1. The laboratory identifies safety and security risks associated with the environment of care that could affect patients, staff, and other people coming to the laboratory’s facilities.

   **Note:** Risks are identified from internal sources such as ongoing monitoring of the environment, results of root cause analyses, results of proactive risk assessments of high-risk processes, and from credible external sources such as Sentinel Event Alerts.
3. The laboratory takes action to minimize or eliminate identified safety and security risks associated with the physical environment.

5. The laboratory maintains all grounds and equipment.

**Note 1:** When the laboratory is located within a hospital, the hospital is responsible for maintenance of the grounds.

**Note 2:** For additional requirements regarding laboratory equipment, please refer to Standards EC.02.04.01 and EC.02.04.03.

7. The laboratory identifies individuals permitted to enter its facilities.

**Note:** Determination of those individuals requiring identification and the method for doing so is at the laboratory’s discretion.

8. The laboratory controls access to and from areas it identifies as security sensitive.

11. The laboratory acts in accordance with product notices and recalls.

12. The laboratory establishes safety policies and procedures that are distributed, practiced, enforced, and reviewed as defined by the laboratory.

**Standard EC.02.01.03**

The laboratory prohibits smoking.

**Element of Performance for EC.02.01.03**

1. Smoking is not permitted in the laboratory and areas under the control of the laboratory.

**Note:** The scope of this EP is concerned with all smoking types—tobacco, electronic, or other.

**Standard EC.02.02.01**

The laboratory manages risks related to hazardous materials and waste.

**Rationale for EC.02.02.01**

Hazardous materials and waste cause harm if they are not managed properly. Examples of such materials include chemicals (such as cleaning products, solvents, and pesticides), compressed gases, and hazardous energy sources. Federal, state, or local regulations often guide the handling, use, and storage of hazardous materials and waste. The laboratory identifies materials it uses that need special handling to minimize the risks of unsafe use and improper disposal.
This chapter previously addressed infectious and regulated medical waste, but this requirement has moved to the “Infection Prevention and Control” (IC) chapter. Nevertheless, it is important for laboratories to be aware that the presence of these substances in the environment could be harmful to staff.

**Note:** *This standard does not address oxygen because it is not a “hazardous material.” Oxygen is covered under the safety standard, EC.02.01.01. However, other substances such as blood are covered by this standard.*

### Elements of Performance for EC.02.02.01

1. ☐ The laboratory maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation. *(See also IC.02.01.01, EP 6)*

3. ☐ The laboratory has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures. *(See also IC.02.01.01, EP 3)*

4. ☐ The laboratory implements its procedures in response to hazardous material and waste spills or exposures. *(See also IC.02.01.01, EP 2)*

5. ☐ The laboratory minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals.

6. ☐ The laboratory minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of radioactive materials. *(See also QSA.19.01.01, EP 2)*

7. ☐ The laboratory minimizes risks associated with the selection and use of hazardous energy sources.

   **Note:** *Hazardous energy sources include, but are not limited to, those generated while using electron microscopy.*

9. ☐ The laboratory implements processes to minimize risks associated with the selection, handling, storage, transport, use, and disposing of hazardous gases and vapors.

   **Note:** *Hazardous gases and vapors include, but are not limited to, glutaraldehyde, formalin, and xylene.*
10. The laboratory monitors levels of hazardous gases and vapors to determine that they are in safe range.†

   **Note:** Law and regulation determine the frequency of monitoring hazardous gases and vapors as well as acceptable ranges.

11. ☐ For managing hazardous materials and waste, the laboratory has the permits, licenses, manifests, and safety data sheets required by law and regulation.

12. The laboratory labels hazardous materials and waste. Labels identify the contents and hazard warnings.‡ *(See also IC.02.01.01, EP 6)*

**Standard EC.02.03.01**

The laboratory manages fire risks.

**Rationale for EC.02.03.01**

The laboratory’s plan for fire response is an essential part of achieving a fire-safe environment. It is important that this response be evaluated in drill scenarios or actual fire situations in order to assess performance of staff and fire safety equipment. Testing the fire response plan should involve realistic situations, although actual evacuation of patients during the drills is not required.

**Elements of Performance for EC.02.03.01**

1. The laboratory minimizes the potential for harm from fire, smoke, and other products of combustion.

3. When a laboratory is part of an accredited organization, it works with the accredited organization to establish mutual responsibilities for fire safety activities.

   **Note:** When the laboratory is located in an accredited organization’s building(s), compliance with the Life Safety Code for the laboratory is the responsibility of the accredited organization. The laboratory should, however, request information on any Life Safety Code deficiencies that might compromise its safety.

4. The laboratory maintains free and unobstructed access to all exits.


‡ The National Fire Protection Association (NFPA) and the Occupational Safety and Health Administration’s (OSHA) Bloodborne Pathogens and Hazard Communications Standards provide details on labeling requirements.
9. ☐️ **For independent laboratories that are not owned by or affiliated with a health care organization, such as a reference lab:** The laboratory has a written fire response plan.

10. The written fire response plan describes the specific roles of staff and licensed independent practitioners at and away from a fire’s point of origin, including when and how to sound fire alarms, how to contain smoke and fire, how to use a fire extinguisher, and how to evacuate to areas of refuge.

13. The laboratory meets all other Health Care Facilities Code fire protection requirements, as related to NFPA 99-2012: Chapter 15.

**Standard EC.02.03.03**

The laboratory conducts fire drills.

**Elements of Performance for EC.02.03.03**

2. The laboratory conducts fire drills every 12 months from the date of the last drill in all freestanding buildings classified as business occupancies and in which patients are seen or treated.

   **Note 1:** When a laboratory shares a building with others, drills need to be conducted only in areas that the laboratory occupies.

   **Note 2:** An organizationwide fire drill meets this requirement for laboratories that are part of an accredited organization.

5. ☐️ The laboratory critiques fire drills to evaluate fire safety equipment, fire safety building features, and staff response to fire. The critiques are documented.

**Standard EC.02.03.05**

The laboratory maintains fire safety equipment and fire safety building features.

**Note:** This standard does not require laboratories to have the types of fire safety equipment and building features described in the elements of performance of this standard. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.

**Elements of Performance for EC.02.03.05**

15. ☐️ At least monthly, the laboratory inspects portable fire extinguishers. The completion dates of the inspections are documented.
Note 1: There are many ways to document the inspections, such as using bar-coding equipment, using check marks on a tag, or using an inventory.

Note 2: Inspections involve a visual check for the presence and correct type of extinguisher, broken parts, full charge, and ease of access.

Note 3: For additional guidance on inspection of fire extinguishers, see NFPA 10, Standard for Portable Fire Extinguishers, 1998 edition (Sections 1-6, 4-3, and 4-4).

16. Every 12 months, the laboratory performs maintenance on portable fire extinguishers. The completion date of the maintenance is documented.

Note 1: There are many ways to document the maintenance, such as using bar-coding equipment, using check marks on a tag, or using an inventory.

Note 2: For additional guidance on maintaining fire extinguishers, see NFPA 10, 1998 edition (Sections 1-6, 4-3, and 4-4).

21. The laboratory tests fire-alarm and fire-detection systems in time frames it establishes. The completion date of the tests is documented.

22. Every 12 months, the laboratory performs preventive maintenance on fire-alarm and fire-detection system components. The completion date of the maintenance is documented.

23. Every 12 months, the laboratory inspects and tests (with or without discharge) automatic fire-extinguishing systems. The completion date of the tests is documented.

24. Fans or dampers in air-handling and smoke-management systems are functional.

Standard EC.02.04.01
The laboratory manages laboratory equipment risks.

Elements of Performance for EC.02.04.01

2. The laboratory maintains a written inventory of laboratory equipment and equipment incident history. The laboratory evaluates new types of equipment before initial use to determine whether they should be included in the inventory.

3. The laboratory identifies, in writing, the activities and frequencies for inspecting, testing (including function checks), and maintaining laboratory equipment based on the following:
   - Manufacturers’ recommendations when available
- Identified risks
- Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) guidelines
- History and experience with the laboratory equipment

*(See also QSA.02.02.01, EP 5)*

**Note:** This requirement also applies whenever the laboratory modifies commercially available equipment or for equipment that is used in a test system developed by the laboratory.

5. The laboratory monitors and reports all incidents in which laboratory equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.

**Note:** Laboratory equipment includes instruments and machines intended for use in diagnosing disease or other conditions.

**Standard EC.02.04.03**

The laboratory inspects, tests, and maintains laboratory equipment.

**Elements of Performance for EC.02.04.03**

4. ⬤ The laboratory conducts performance testing of and maintains all sterilizers (autoclaves). These activities are documented. *(See also IC.02.02.01, EP 2)*

6. ⬤ The laboratory documents major repairs and parts replacement for each instrument or piece of equipment, for the life of the instrument or equipment.

7. ⬤ The laboratory performs preventive maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.

9. ⬤ The laboratory evaluates analytic measuring equipment and instruments for all critical operating characteristics. This evaluation is documented.

11. ⬤ The laboratory evaluates automated volumetric equipment. This evaluation is documented.

12. ⬤ The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers’ guidelines. The temperature is documented.
13. For each instrument or piece of equipment, the laboratory retains any daily, weekly, monthly, quarterly, or semiannual performance testing and function checks for at least two years.

14. All blood warmers must have a warning system to detect malfunctions and prevent damage to the cellular components. This system should be checked per manufacturers’ specifications.

15. Staff standardize scales used for phlebotomy and blood collection with a container of known mass or volume each day before use and after repairs/adjustments in order to verify that the correct volume of blood is being drawn.

17. The laboratory evaluates the accuracy of analytical balances using ANSI/ASTM Class standard weights. This evaluation is documented.

27. The laboratory meets all other Health Care Facilities Code requirements for electrical equipment in a patient’s vicinity as related to NFPA 99-2012: Chapter 10.

**Standard EC.02.04.05**

The laboratory monitors the performance of the flow cytometry instrument.

**Elements of Performance for EC.02.04.05**

1. The laboratory has written procedures for flow cytometry that address instrument performance including: Verification of alignment of instrument optical components. *(See also DC.02.01.05, EP 2)*

2. The laboratory has written procedures for flow cytometry that address instrument performance including: Calibration with fluorescent detector bead(s) or cell(s) runs each day that the flow cytometer is in use. *(See also DC.02.01.05, EP 2)*

3. The laboratory has written procedures for flow cytometry that address instrument performance including: Verification of color compensation settings whenever cells are labeled with more than one fluorescent reagent. *(See also DC.02.01.05, EP 2)*

4. The laboratory has written procedures for flow cytometry that address instrument performance including: Detection of and adjustment for shifts in light scatter characteristics each day of use to provide consistent day-to-day instrument readings. *(See also DC.02.01.05, EP 2)*
5. The laboratory documents and maintains records of the flow cytometry instrument performance. *(See also DC.02.01.05, EP 2)*

**Standard EC.02.05.01**

The laboratory manages risks associated with its utility systems.

**Elements of Performance for EC.02.05.01**

3. The laboratory maintains a written inventory of all operating components of utility systems or maintains a written inventory of selected operating components of utility systems based on risks for infection, occupant needs, and systems critical to laboratory services. The laboratory evaluates new types of utility components before initial use to determine whether they should be included in the inventory.

*Note:* A laboratory within an accredited organization that has an inventory can substitute that inventory for its own, as long as the laboratory has input into its formation.

4. The laboratory identifies, in writing, the activities for inspecting, testing, and maintaining all operating components of utility systems on the inventory. The activities are based on criteria such as manufacturers’ recommendations, risk levels, and laboratory experience.

*Note:* Laboratories may use different approaches to maintenance. For example, activities such as predictive maintenance, reliability-centered maintenance, interval-based maintenance, corrective maintenance, or metered maintenance may be selected to provide for dependable performance.

5. The laboratory identifies, in writing, the intervals for inspecting, testing, and maintaining all operating components of the utility systems on the inventory, based on criteria such as manufacturers’ recommendations, risk levels, or laboratory experience.

7. In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies.

8. The laboratory maps the distribution of its utility systems.

9. The laboratory labels utility system controls so that staff are able to partially or completely shut down systems in emergencies.
10. The laboratory has written procedures for responding to utility system disruptions.

11. The laboratory’s procedures address shutting off the malfunctioning system and notifying staff in affected areas.

12. The laboratory’s procedures address performing emergency clinical interventions during utility system disruptions.

13. The laboratory responds to utility system disruptions as described in its procedures.

**Standard EC.02.05.03**

The laboratory has a reliable emergency electrical power source.

**Elements of Performance for EC.02.05.03**

1. For laboratories that were constructed, or had a change in occupancy type, or have undergone an electrical system upgrade since 1983, the laboratory has a Type 1 or Type 3 essential electrical system in accordance with NFPA 99, 2012 edition. This essential electrical system must be divided into three branches, including the life safety branch, critical branch, and equipment branch. Both the life safety branch and the critical branch are kept independent of all other wiring and equipment, and they transfer within 10 seconds of electrical interruption. Each branch has at least one automatic transfer switch. For additional guidance, see NFPA 99-2012: 6.4.2.2

The laboratory provides emergency power within 10 seconds for the following:

2. Alarm systems, as required by the *Life Safety Code*.

   **Note:** *For guidance in establishing a reliable emergency power system (that is, an essential electrical distribution system), see NFPA 99-2012: 6.4.1.1; 6.4.2.2; NFPA 110-2010: 4.1; Table 4.1(b).*

The laboratory provides emergency power for the following:

3. Exit route and exit sign illumination, as required by the *Life Safety Code*.

   **Note:** *For guidance in establishing a reliable emergency power system (that is, an essential electrical distribution system), see NFPA 99-2012: 6.4.1.1; 6.4.2.2; NFPA 110-2010: 4.1; Table 4.1(b).*

4. Emergency communication systems, as required by the *Life Safety Code*. 

Note: For guidance in establishing a reliable emergency power system (that is, an essential electrical distribution system), see NFPA 99-2012: 6.4.2.2; NFPA 110-2010: 4.1; Table 4.1(b).

8. Blood, bone, and tissue storage units.

9. Essential refrigeration and heating as identified by the laboratory, such as designated refrigerators, freezers, and incubators.

10. Essential laboratory equipment as identified by the laboratory, such as blood gas equipment in a stat lab.

**Standard EC.02.05.05**

The laboratory inspects, tests, and maintains utility systems.

**Note:** At times, maintenance is performed by an external service. In these cases, laboratories are not required to possess maintenance documentation but have access to such documentation during survey and as needed.

**Elements of Performance for EC.02.05.05**

1. The laboratory tests utility system components on the inventory before initial use. The completion date of the tests is documented.

The laboratory inspects, tests, and maintains the following:

5. Non-life-support utility system components on the inventory. These activities are documented.

8. The laboratory meets all other Health Care Facilities Code requirements for electrical systems and heating, ventilation, and air conditioning (HVAC) as related to NFPA 99-2012: Chapters 6 and 9.

**Standard EC.02.05.07**

The laboratory inspects, tests, and maintains emergency power systems.

**Note:** This standard does not require laboratories to have the types of emergency power equipment described in the elements of performance of this standard. However, if these types of equipment exist within the building, then the following maintenance, testing, and inspection requirements apply.
Rationale for EC.02.05.07
Emergency electrical power supply systems may fail during a power disruption, leaving the laboratory unable to deliver laboratory services to patients. Testing these systems for sufficient lengths of time at regular frequencies increases the likelihood of detecting reliability problems and reduces the risk of losing this critical resource when it is most needed.

Elements of Performance for EC.02.05.07

1. At least monthly, the laboratory performs a functional test of emergency lighting systems and exit signs required for egress and task lighting for a minimum duration of 30 seconds. The completion date of the test is documented. (For full text, refer to NFPA 101-2012: 7.9.3; 7.10.9; NFPA 99-2012: 6.3.2.2.11.5)

2. Every 12 months, the laboratory either performs a functional test of battery-powered lights required for egress and exit signs for a duration of 1½ hours. The test results and completion dates are documented. (For full text, refer to NFPA 101-2012: 7.9.3; 7.10.9; NFPA 99-2012: 6.3.2.2.11.5)

3. Every quarter, the laboratory performs a functional test of stored emergency power supply systems (SEPSS) for 5 minutes or as specified for its class (whichever is less). The laboratory performs an annual test at full load for 60% of the full duration of its class. The completion dates of the tests are documented.

Note 1: Non–SEPSS battery backup emergency power systems that the laboratory has determined to be critical for operations during a power failure (for example, laboratory equipment or electronic medical records) should be properly tested and maintained in accordance with manufacturers’ recommendations.

Note 2: SEPSS are intended to automatically supply illumination or power to critical areas and equipment essential for safety to human life. Included are systems that supply emergency power for such functions as illumination for safe exiting, ventilation where it is essential to maintain life, fire detection and alarm systems, public safety communications systems, and processes where the current interruption would produce serious life safety or health hazards to patients, the public, or staff.

Note 3: Class defines the minimum time for which the SEPSS is designed to operate at its rated load without being recharged. For additional guidance, see NFPA 111, Standard on Stored Electrical Energy Emergency and Standby Power Systems, 1996 edition.
4. At least weekly, the laboratory inspects the emergency power supply system (EPSS), including all associated components and batteries. The results and completion dates of weekly inspections are documented. (For full text, refer to NFPA 110-2010: 8.3.1; 8.3.3; 8.3.4; 8.4.1)

5. At least monthly, the laboratory tests each emergency generator beginning with a cold start under load for at least 30 continuous minutes. The cooldown period is not part of the 30 continuous minutes. The test results and completion dates are documented. (For full text, refer to NFPA 99-2012: 6.4.4.1)

6. The monthly tests for diesel-powered emergency generators are conducted with a dynamic load that is at least 30% of the nameplate rating of the generator or meets the manufacturer’s recommended prime movers’ exhaust gas temperature. If the laboratory does not meet either the 30% of nameplate rating or the recommended exhaust gas temperature during any test in EC.02.05.07, EP 5, then it must test the emergency generator once every 12 months using supplemental (dynamic or static) loads of 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 1½ continuous hours. (For full text, refer to NFPA 99-2012: 6.4.4.1)

   **Note:** Tests for non-diesel-powered generators need only be conducted with available load.

7. At least monthly, the laboratory tests all automatic and manual transfer switches on the inventory. The test results and completion dates are documented. (For full text, refer to NFPA 99-2012: 6.4.4.1)

8. At least once every 36 months, laboratories with a generator providing emergency power for the services test each emergency generator for a minimum of 4 continuous hours. The test results and completion dates are documented.

   **Note:** For additional guidance, see NFPA 110-2010, Chapter 8.

9. The 36-month diesel-powered emergency generator test uses a dynamic or static load that is at least 30% of the nameplate rating of the generator or meets the manufacturer’s recommended prime movers’ exhaust gas temperature.

   **Note 1:** Tests for non-diesel-powered generators need only be conducted with available load.

   **Note 2:** For additional guidance, see NFPA 110-2010, Chapter 8.
**Introduction to Standard EC.02.06.01**

Features of the laboratory’s space influence patient outcomes and satisfaction and promote patient safety. The physical space also affects staff and others in the laboratory.

These features of the environment of care include the following:

- Quality of natural and artificial light
- Privacy
- Size and configuration of space
- Security
- Clear access to internal and external doors
- Level of noise
- Space that allows staff to work efficiently

When designed into and managed as part of the environment, these elements create safe and suitable surroundings that support patient dignity and allow ease of interaction.

The standards do not specifically address all of these features. However, laboratories may wish to consider these aspects of the environment when they design and manage spaces. Decisions on what features to pursue should be based on data, such as data collected from staff and evidence-based design guidelines.

**Standard EC.02.06.01**

The laboratory establishes and maintains a safe, functional environment.

**Elements of Performance for EC.02.06.01**

13. The laboratory maintains ventilation, temperature, and humidity levels suitable for the laboratory services provided.

28. Work areas have enough space and are configured to efficiently handle and house equipment and reagents. The features of work areas do not adversely affect test outcomes or compromise staff safety.

29. Equipment, instruments, reagents, materials, and supplies are provided for the type and volume of testing the laboratory performs.

30. All laboratory areas are safe for staff and visitors.

31. Molecular amplification procedures that are not contained in closed systems have a unidirectional workflow that includes separate areas for specimen preparation, amplification and product detection, and reagent preparation.
32. Eye wash stations are readily accessible to laboratory staff.

Note: For guidance in providing adequate eyewash stations, see Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.10.151(c) and the American National Standard for Eyewash and Shower Equipment ANSI/ISEA Z358.1-2009 (created by the International Safety Equipment Association [ISEA] and approved by the American National Standards Institute [ANSI]).

37. The laboratory does not allow food or drink to be stored in work areas that contain blood, reagents, or other potentially infectious agents.

Standard EC.02.06.05
The laboratory manages its environment during demolition, renovation, or new construction to reduce risk to those in the laboratory.

Rationale for EC.02.06.05
In addition to fire safety, there are other hazards and risks resulting from demolition, renovation, or new construction that must be addressed. It is important to plan and conduct risk assessments before construction begins. Authoritative guidelines and state regulations can provide valuable information to guide demolition, renovation, or new construction.

Elements of Performance for EC.02.06.05
1. When planning for new, altered, or renovated space, the laboratory uses one of the following design criteria:
   - State rules and regulations
   - Laboratory design guidelines published by the Clinical Laboratory Standards Institute

   When the above rules, regulations, and guidelines do not meet specific design needs, the laboratory uses other reputable standards and guidelines that provide equivalent design criteria.

5. When site conditions or specific clinical needs require modification of design criteria, the laboratory identifies the need to train staff about using space and equipment.
Standard EC.03.01.01

Staff and licensed independent practitioners are familiar with their roles and responsibilities relative to the environment of care.

Rationale for EC.03.01.01

People are the key to successfully managing risks in the physical environment. Plans and procedures are of no value if those who work in the laboratory do not know how to follow them. Everyone who works in the laboratory is responsible for safety, and it is important for them to know how to identify and minimize risks, what actions to take when an incident occurs, and how to report it.

Element of Performance for EC.03.01.01

2. Staff and licensed independent practitioners can describe or demonstrate actions to take in the event of an environment of care incident.

Introduction to Standard EC.04.01.01

Most laboratories are able to manage their physical space because they typically use all areas on a daily basis, making it easier for staff to monitor environment of care issues. Monitoring includes keeping track of injuries; occupational illness and injuries to staff; property damage or loss; security incidents; hazardous materials and waste spills and exposures; and fire safety equipment and utility management problems, failures, or use errors.

Quickly identifying and resolving actual and potential environment of care problems is crucial. Laboratories are often able to resolve environmental issues without formal reporting processes. However, when reporting processes are more informal, the laboratory faces a greater risk of overlooking important patterns or trends. Staff reports and their resolution can be a sign of how comprehensively and effectively the risk assessments, as described in the management plans, have been conducted. Consistently investigating and resolving staff reports about environmental issues can lead to safer delivery of laboratory services.

Standard EC.04.01.01

The laboratory collects information to monitor conditions in the environment.
Elements of Performance for EC.04.01.01

1. The laboratory establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
   - Injuries to patients or others within the laboratory
   - Occupational illnesses and staff injuries
   - Incidents of damage to its property or the property of others in locations it controls
   - Security incidents involving patients, staff, or others in locations it controls
   - Hazardous materials and waste spills and exposures
   - Fire safety management problems, deficiencies, and failures
   - Laboratory equipment management problems, failures, and use errors
   - Utility systems management problems, failures, or use errors

Note 1: All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.

Note 2: Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve laboratory services, or to prevent similar incidents, are not lost as a result of following the legal process.

The laboratory reports and investigates the following:

3. Injuries occurring in the laboratory.
4. Occupational illnesses and staff injuries.
5. Incidents of damage to its property or the property of others in locations it controls.
6. Security incidents involving patients, staff, or others in locations it controls.
8. Hazardous materials and waste spills and exposures.
10. Laboratory equipment management problems, failures, and use errors.
11. Utility systems management problems, failures, or use errors.
15. Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan’s objectives, scope, performance, and effectiveness.

**Standard EC.04.01.03**
The laboratory analyzes identified environment of care issues.

**Element of Performance for EC.04.01.03**
2. The laboratory uses the results of data analysis to identify opportunities to resolve environmental safety issues.

**Standard EC.04.01.05**
The laboratory improves its environment of care.

**Element of Performance for EC.04.01.05**
1. The laboratory takes action on the identified opportunities to resolve environmental safety issues.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

Is the no-smoking policy up-to-date and enforced as written? (EC.02.01.03)

Have all hazardous materials and waste been identified and addressed in the spills and exposure plan? (EC.02.02.01)

**TIP:** Review inventory and evaluate all hazardous materials and waste; also evaluate laboratory’s policy with managing such materials.

Are the staff trained to handle emergency and fire situations? When were fire drills conducted over the past year? (EC.02.03.01, EC 02.03.03, EC.02.03.05)

Is there a systematic process for maintaining, inspecting, and testing laboratory equipment and instruments? (EC.02.04.01, EC.02.04.03)
TIP: For each piece of laboratory equipment and instrument (including blood warmers, sterilizers, flow cytometry, analytical balance, volumetric equipment, etc.), create an equipment log that captures the following:

- Regularly scheduled preventive maintenance and performance testing
- Proper evaluation of automated equipment and instruments
- For temperature-monitored equipment and environment (such as morgue and reagent storage rooms), include a temperature recording sheet with acceptable ranges
- Management, reporting, and corrective action for each incident and malfunction

What is the laboratory’s plan for electrical power interruption? Is there a backup power system that can maintain a safe, functional laboratory environment considering requirements for ventilation, refrigeration, temperature, and humidity? (EC.02.05.03, EC.02.05.07)

TIP: Review staff’s compliance with monitoring temperature and checking alarm systems. If temperature documentation is computerized, confirm that documentation can be retrieved by date and time and that records are retained for the appropriate amount of time (see Appendix A on Retention Times for Records, Reports, and Specimens).
**Written Documentation Checklist**

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC.01.01.01, EP 4</td>
<td>The laboratory has a written plan for providing a safe environment for everyone who enters the laboratory’s facilities.</td>
</tr>
<tr>
<td>EC.01.01.01, EP 5</td>
<td>The laboratory has a written plan for providing a secure environment for everyone who enters the laboratory’s facilities.</td>
</tr>
<tr>
<td>EC.01.01.01, EP 6</td>
<td>The laboratory has a written plan for managing the following: Hazardous materials and waste.</td>
</tr>
<tr>
<td>EC.01.01.01, EP 7</td>
<td>The laboratory has a written plan for managing the following: Fire safety.</td>
</tr>
<tr>
<td>EC.01.01.01, EP 8</td>
<td>The laboratory has a written plan for managing the following: Laboratory equipment.</td>
</tr>
<tr>
<td>EC.01.01.01, EP 9</td>
<td>The laboratory has a written plan for managing the following: Utility systems.</td>
</tr>
<tr>
<td>EC.02.02.01, EP 1</td>
<td>The laboratory maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. The only materials that need to be included on the inventory are those whose handling, use, and storage are addressed by law and regulation. <em>(See also IC.02.01.01, EP 6)</em></td>
</tr>
<tr>
<td>EC.02.02.01, EP 3</td>
<td>The laboratory has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures. <em>(See also IC.02.01.01, EP 3)</em></td>
</tr>
<tr>
<td>EC.02.02.01, EP 11</td>
<td>For managing hazardous materials and waste, the laboratory has the permits, licenses, manifests, and safety data sheets required by law and regulation.</td>
</tr>
<tr>
<td>EC.02.03.01, EP 9</td>
<td>For independent laboratories that are not owned by or affiliated with a health care organization, such as a reference lab: The laboratory has a written fire response plan.</td>
</tr>
<tr>
<td>EC.02.03.03, EP 5</td>
<td>The laboratory critiques fire drills to evaluate fire safety equipment, fire safety building features, and staff response to fire. The critiques are documented.</td>
</tr>
</tbody>
</table>
| EC.02.03.05, EP 15 | At least monthly, the laboratory inspects portable fire extinguishers. The completion dates of the inspections are documented.  
**Note 1:** There are many ways to document the inspections, such as using bar-coding equipment, using check marks on a tag, or using an inventory.  
**Note 2:** Inspections involve a visual check for the presence and correct type of extinguisher, broken parts, full charge, and ease of access.  
**Note 3:** For additional guidance on inspection of fire extinguishers, see NFPA 10, Standard for Portable Fire Extinguishers, 1998 edition (Sections 1-6, 4-3, and 4-4). |
| EC.02.03.05, EP 16 | Every 12 months, the laboratory performs maintenance on portable fire extinguishers. The completion date of the maintenance is documented.  
**Note 1:** There are many ways to document the maintenance, such as using bar-coding equipment, using check marks on a tag, or using an inventory.  
**Note 2:** For additional guidance on maintaining fire extinguishers, see NFPA 10, 1998 edition (Sections 1-6, 4-3, and 4-4). |
| EC.02.03.05, EP 21 | The laboratory tests fire-alarm and fire-detection systems in time frames it establishes. The completion date of the tests is documented. |
| EC.02.03.05, EP 22 | Every 12 months, the laboratory performs preventive maintenance on fire-alarm and fire-detection system components. The completion date of the maintenance is documented. |
| EC.02.03.05, EP 23 | Every 12 months, the laboratory inspects and tests (with or without discharge) automatic fire-extinguishing systems. The completion date of the tests is documented. |
| EC.02.04.01, EP 2 | The laboratory maintains a written inventory of laboratory equipment and equipment incident history. The laboratory evaluates new types of equipment before initial use to determine whether they should be included in the inventory. |
| EC.02.04.01, EP 3 | The laboratory identifies, in writing, the activities and frequencies for inspecting, testing (including function checks), and maintaining laboratory equipment based on the following:  
- Manufacturers’ recommendations when available  
- Identified risks  
- Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) guidelines  
- History and experience with the laboratory equipment (See QSA.02.02.01, EP 5) |
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC.02.04.03, EP 4</td>
<td>The laboratory conducts performance testing of and maintains all sterilizers (autoclaves). These activities are documented. <em>(See also IC.02.02.01, EP 2)</em></td>
</tr>
<tr>
<td>EC.02.04.03, EP 6</td>
<td>The laboratory documents major repairs and parts replacement for each instrument or piece of equipment, for the life of the instrument or equipment.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 7</td>
<td>The laboratory performs preventive maintenance, periodic inspection, and performance testing of each instrument or piece of equipment. These activities are documented.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 9</td>
<td>The laboratory evaluates analytic measuring equipment and instruments for all critical operating characteristics. This evaluation is documented.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 11</td>
<td>The laboratory evaluates automated volumetric equipment. This evaluation is documented.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 12</td>
<td>The laboratory monitors temperature-controlled spaces and equipment at frequencies established by the laboratory, using manufacturers' guidelines. The temperature is documented.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 13</td>
<td>For each instrument or piece of equipment, the laboratory retains any daily, weekly, monthly, quarterly, or semiannual performance testing and function checks for at least two years.</td>
</tr>
<tr>
<td>EC.02.04.03, EP 17</td>
<td>The laboratory evaluates the accuracy of analytical balances using ANSI/ASTM Class standard weights. This evaluation is documented.</td>
</tr>
<tr>
<td>EC.02.04.05, EP 1</td>
<td>The laboratory has written procedures for flow cytometry that address instrument performance including: Verification of alignment of instrument optical components. <em>(See also DC.02.01.05, EP 2)</em></td>
</tr>
<tr>
<td>EC.02.04.05, EP 5</td>
<td>The laboratory documents and maintains records of the flow cytometry instrument performance. <em>(See also DC.02.01.05, EP 2)</em></td>
</tr>
</tbody>
</table>
| EC.02.05.01, EP 3 | The laboratory maintains a written inventory of all operating components of utility systems or maintains a written inventory of selected operating components of utility systems based on risks for infection, occupant needs, and systems critical to laboratory services. The laboratory evaluates new types of utility components before initial use to determine whether they should be included in the inventory.  
**Note:** A laboratory within an accredited organization that has an inventory can substitute that inventory for its own, as long as the laboratory has input into its formation. |
<table>
<thead>
<tr>
<th>Code</th>
<th>EP</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC.02.05.01, EP 4</td>
<td>The laboratory identifies, in writing, the activities for inspecting, testing, and maintaining all operating components of utility systems on the inventory. The activities are based on criteria such as manufacturers’ recommendations, risk levels, and laboratory experience. <strong>Note:</strong> Laboratories may use different approaches to maintenance. For example, activities such as predictive maintenance, reliability-centered maintenance, interval-based maintenance, corrective maintenance, or metered maintenance may be selected to provide for dependable performance.</td>
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<tr>
<td>EC.02.05.01, EP 5</td>
<td>The laboratory identifies, in writing, the intervals for inspecting, testing, and maintaining all operating components of the utility systems on the inventory, based on criteria such as manufacturers' recommendations, risk levels, or laboratory experience.</td>
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</tr>
<tr>
<td>EC.02.05.01, EP 8</td>
<td>The laboratory maps the distribution of its utility systems.</td>
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<tr>
<td>EC.02.05.01, EP 10</td>
<td>The laboratory has written procedures for responding to utility system disruptions.</td>
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<tr>
<td>EC.02.05.05, EP 1</td>
<td>The laboratory tests utility system components on the inventory before initial use. The completion date of the test is documented.</td>
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<tr>
<td>EC.02.05.07, EP 1</td>
<td>At least monthly, the laboratory performs a functional test of emergency lighting systems and exit signs required for egress and task lighting for a minimum duration of 30 seconds. The completion date of the test is documented. <strong>(For full text, refer to NFPA 101-2012: 7.9.3; 7.10.9; NFPA 99-2012: 6.3.2.2.11.5)</strong></td>
<td></td>
</tr>
<tr>
<td>EC.02.05.07, EP 2</td>
<td>Every 12 months, the laboratory either performs a functional test of battery-powered lights required for egress and exit signs for a duration of 1 1/2 hours. The test results and the completion dates are documented. <strong>(For full text, refer to NFPA 101-2012: 7.9.3; 7.10.9; NFPA 99-2012: 6.3.2.2.11.5)</strong></td>
<td></td>
</tr>
<tr>
<td>EC.02.05.07, EP 3</td>
<td>Every quarter, the laboratory performs a functional test of stored emergency power supply systems (SEPSS) for 5 minutes or as specified for its class (whichever is less). The laboratory performs an annual test at full load for 60% of the full duration of its class. The completion dates of the tests are documented.</td>
<td></td>
</tr>
</tbody>
</table>
### Environment of Care

**Note 1:** Non-SEPSS battery backup emergency power systems that the laboratory has determined to be critical for operations during a power failure (for example, laboratory equipment or electronic medical records) should be properly tested and maintained in accordance with manufacturers’ recommendations.

**Note 2:** SEPSS are intended to automatically supply illumination or power to critical areas and equipment essential for safety to human life. Included are systems that supply emergency power for such functions as illumination for safe exiting, ventilation where it is essential to maintain life, fire detection and alarm systems, public safety communications systems, and processes where the current interruption would produce serious life safety or health hazards to patients, the public, or staff.

**Note 3:** Class defines the minimum time for which the SEPSS is designed to operate at its rated load without being recharged. For additional guidance, see NFPA 111, Standard on Stored Electrical Energy Emergency and Standby Power Systems, 1996 edition.

| EC.02.05.07, EP 4 | At least weekly, the laboratory inspects the emergency power supply system (EPSS), including all associated components and batteries. The results and completion dates of weekly inspections are documented. (For full text refer to NFPA 110-2010: 8.3.1; 8.3.3; 8.3.4; 8.4.1) |
| EC.02.05.07, EP 5 | At least monthly, the laboratory tests each emergency generator beginning with a cold start under load for at least 30 continuous minutes. The cooldown period is not part of the 30 continuous minutes. The test results and completion dates of the tests are documented. (For full text, refer to NFPA 99-2012: 6.4.4.1) |
| EC.02.05.07, EP 7 | At least monthly, the laboratory tests all automatic and manual transfer switches on the inventory. The test results and completion dates are documented. (For full text, refer to NFPA 99-2012: 6.4.4.1) |
| EC.02.05.07, EP 9 | At least once every 36 months, laboratories with a generator providing emergency power for the services test each emergency generator for a minimum of 4 continuous hours. The test results and completion dates are documented. **Note:** For additional guidance, see NFPA 110, 2005 edition, Standard for Emergency & Standby Power Systems-2010, Chapter 8. |
# Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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<tbody>
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</table>
Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Emergency Management (EM)

Overview

Emergencies can threaten any health care organization. A single emergency can temporarily disrupt services; however, multiple emergencies that occur concurrently or sequentially can adversely impact patient safety and the laboratory’s ability to provide services for an extended length of time. This is particularly true in situations where the community cannot adequately support an organization. Emergencies of this severity are considered disasters. Power failures, water and fuel shortages, flooding, and communication breakdowns are just a few of the hazards that can disrupt laboratory services and pose risks to the laboratory and its staff.

Emergency management consists of four phases: mitigation, preparedness, response, and recovery. These phases occur over time; mitigation and preparedness generally occur before an emergency, and response and recovery occur during and after an emergency. The precursor activity to mitigation is the identification of risks and vulnerabilities—hazards, threats, and adverse events that could impact laboratory services. Some organizations refer to this process as a hazard vulnerability analysis. Identifying risks and vulnerabilities is the first step toward composing a comprehensive Emergency Operations Plan (EOP). The EOP document may reflect response strategies ranging from continuing a full scope of services, to rescheduling nonurgent appointments, to closing temporarily.

If the laboratory is part of a Joint Commission–accredited organization that meets the requirements of this chapter, the laboratory is not required to have a separate EOP; however, the laboratory’s leaders are required to participate in the development of the overall organizational EOP. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting all requirements in this chapter.

No organization can predict the nature of a future emergency, nor can it predict the date of its arrival. However, laboratories can plan for managing the following critical areas so that they can respond effectively regardless of the cause(s) of an emergency:

- Communications
- Resources and assets
- Security
Staff responsibilities
Utilities
Patient clinical and support activities

When organizations consider their capabilities in these areas, they are taking an “all hazards” approach to emergency management that supports a level of preparedness sufficient to address a range of emergencies, regardless of the cause. This approach lays the foundation for developing an EOP that is scalable to emergencies that may escalate in complexity, scope, or duration. For the most extreme type of emergencies—disasters—additional human resources may be necessary. Laboratories can choose to assign responsibilities to volunteer practitioners when such volunteers are essential to carrying out laboratory services. Laboratories should evaluate their planning efforts and test their EOP through exercise scenarios so that they can use the lessons learned to improve the effectiveness of their response strategies.

About This Chapter
The “Emergency Management” (EM) chapter guides organizations through the planning activities that occur prior to developing the EOP. The chapter also describes the essential components that comprise the EOP such as preparedness activities, response procedures, and identification of the staff responsible for these activities. Finally, the chapter guides organizations through evaluating the effectiveness of the EOP.

The planning activities described in Standard EM.01.01.01 help the laboratory to focus its strategy for mitigating the potential effects of emergencies, as well as its preparedness strategy for organizing and mobilizing essential resources. Laboratories may be faced with a range of possible situations: the laboratory itself is damaged in an emergency; a sudden traumatic event (hazardous gas release or earthquake) affects the community; an outbreak of infectious disease creates a surge in demand for laboratory services. The laboratory will use its EOP document (described in Standard EM.02.01.01 and subsequent standards) to define its response to emergencies and to help position it for recovery after the emergency has passed. In addition to the requirements provided in these standards, numerous resources are available to the field (such as the Clinical and Laboratory Standards Institute) that provide detailed technical guidance in emergency response for laboratories. After the EOP is in place, it must be tested through emergency response exercises in order to evaluate its effectiveness and use lessons learned to improve
response strategies (described in Standard EM.03.01.03). Adjustments to the EOP should be made based on emergency response exercises and responses to actual emergencies (described in Standard EM.03.01.03).

Additional standards in other chapters are integral to organizationwide emergency preparedness, including processes for the following:

- Maintaining continuity of information (refer to Standard IM.01.01.03)
- Responding to outbreaks of infectious disease (refer to Standard IC.01.06.01)
Chapter Outline

I. Foundation for the Emergency Operations Plan (EM.01.01.01)

II. The Plan for Response and Recovery
   A. General Requirements (EM.02.01.01)
   B. Specific Requirements
      1. Communications (EM.02.02.01)
      2. Resources and Assets (EM.02.02.03)
      3. Security (EM.02.02.05)
      4. Staff (EM.02.02.07)
      5. Utilities (EM.02.02.09)
      6. Patients (EM.02.02.11)
      7. Disaster Volunteers—Volunteer Practitioners (EM.02.02.15)

III. Evaluation (EM.03.01.03)
Standards, Rationales, and Elements of Performance

Standard EM.01.01.01
The laboratory engages in planning activities prior to developing its Emergency Operations Plan.

Note: An emergency is an unexpected or sudden event that significantly disrupts the laboratory’s environment of care or its ability to provide services. At times, an emergency results in a sudden, increased demand for the laboratory’s services. Emergencies can be either human-made or natural (such as an electrical system failure or a tornado), or a combination of both, and they exist on a continuum of severity. A disaster is a type of emergency that, due to its complexity, scope, or duration, threatens the laboratory’s capabilities and requires outside assistance to sustain patient care, safety, or security functions.

Rationale for EM.01.01.01
An emergency can suddenly and significantly affect demand for the laboratory’s services or its ability to provide those services. Therefore, the laboratory needs to engage in planning activities that prepare it to form the Emergency Operations Plan. These activities include identifying risks, prioritizing likely emergencies, attempting to mitigate them when possible, and considering its potential emergencies in developing strategies for preparedness. Because some emergencies that impact a laboratory originate in the community, the laboratory needs to take advantage of opportunities, where they exist, to collaborate with relevant parties in the community.

Elements of Performance for EM.01.01.01

1. The laboratory’s leaders participate in planning activities prior to developing an Emergency Operations Plan.

2. The laboratory identifies potential emergencies and the direct and indirect effects that these emergencies may have on the need for its services or its ability to provide those services. (See also IC.01.06.01, EP 4)

   Note 1: Some organizations refer to this process as a hazard vulnerability analysis (HVA).

   Note 2: The potential of an emergency situation stemming from a surge in infectious patients is addressed in the “Infection Prevention and Control” (IC) chapter.

3. The laboratory prioritizes the potential emergencies it has identified.
4. The laboratory, either as an independent organization or as part of another organization, communicates its needs and vulnerabilities to community emergency response agencies and identifies the community’s capability to meet its needs.

**Note:** A laboratory, either as part of an accredited organization or as an independent organization, may communicate and integrate with the National Incident Management System, the Laboratory Response Network, or other planning and response entities serving its community.

5. The laboratory uses its prioritized emergencies as a basis for defining mitigation activities (that is, activities designed to reduce the risk of and potential damage from an emergency).

**Note:** Mitigation, preparedness, response, and recovery are the four phases of emergency management. They occur over time: Mitigation and preparedness generally occur before an emergency, and response and recovery occur during and after an emergency.

6. The laboratory uses its prioritized emergencies as a basis for defining the preparedness activities that will organize and mobilize essential resources. (See also IM.01.01.03, EPs 1–4)

**Standard EM.02.01.01**

The laboratory has an Emergency Operations Plan.

**Note 1:** The laboratory’s Emergency Operations Plan (EOP) is designed to coordinate its communications, resources and assets, security, staff responsibilities, utilities, and patient clinical and support activities during an emergency (refer to Standards EM.02.02.01, EM.02.02.03, EM.02.02.05, EM.02.02.07, EM.02.02.09, and EM.02.02.11). Although emergencies have many causes, the effects on these areas of the organization and the required response effort may be similar. This “all hazards” approach supports a general response capability that is sufficiently nimble to address a range of emergencies of different duration, scale, and cause. For this reason, the plan’s response procedures address the prioritized emergencies but are also adaptable to other emergencies that the organization may experience.

**Note 2:** If the laboratory is part of a Joint Commission–accredited organization that meets the requirements of this chapter, the laboratory is not required to have a separate Emergency Operations Plan; however, the laboratory is required to follow a plan, either as part of the overall organizational plan or as a plan specific to the laboratory.
Rationale for EM.02.01.01
A successful response effort relies on a comprehensive and flexible Emergency Operations Plan that guides decision making at the onset of an emergency and as an emergency evolves. Although the Emergency Operations Plan can be designed in a variety of ways, it must address response procedures that are both applicable to the laboratory’s likely emergencies and adaptable in supporting key areas (such as communications and utilities) that could be affected by different types of emergencies. Laboratories that are in hospitals will work collaboratively with the hospital to develop an Emergency Operations Plan that effectively coordinates their respective responsibilities for mitigation, preparedness, response, and recovery.

Elements of Performance for EM.02.01.01

1. The laboratory’s leaders participate in the development of the Emergency Operations Plan.

2. The laboratory has a written Emergency Operations Plan that describes the response procedures to follow when emergencies occur.

   Note: The response procedures address the prioritized emergencies but can also be adapted to other emergencies that the laboratory may experience. Response procedures could include the following:
   - Maintaining or expanding services
   - Conserving resources
   - Curtailing services
   - Relocating services to an alternative site
   - Supplementing resources from outside the local community
   - Closing the laboratory to new patients
   - Staged evacuation
   - Total evacuation

4. The laboratory has a written Emergency Operations Plan that describes the recovery strategies, actions, and individual responsibilities necessary to restore the laboratory’s services after an emergency.

5. The Emergency Operations Plan describes the processes for initiating and terminating the laboratory’s response and recovery phases of the emergency, including under what circumstances these phases are activated.
Note: Mitigation, preparedness, response, and recovery are the four phases of emergency management. They occur over time: Mitigation and preparedness generally occur before an emergency, and response and recovery occur during and after an emergency.

6. The Emergency Operations Plan identifies the individual(s) responsible for activating the response and recovery phases of the emergency response.

Note: Although a primary individual should be designated by role or title, an alternative individual may also be identified to assume this responsibility should the primary individual not be available at the time of an emergency.

8. If the laboratory experiences an actual emergency, the laboratory implements its response procedures related to laboratory services for its patients.

Standard EM.02.02.01
As part of its Emergency Operations Plan, the laboratory prepares for how it will communicate during emergencies.

Rationale for EM.02.02.01
The laboratory maintains reliable communication capabilities and channels for the purpose of communicating response efforts to staff and external organizations. The laboratory establishes backup communication processes and technologies (for example, cell phones, landlines, bulletin boards, fax machines, satellite phones, Amateur Radio, text messages) to communicate essential information if primary communications systems fail.

Elements of Performance for EM.02.02.01
1. The Emergency Operations Plan describes how staff and licensed independent practitioners (such as pathologists) will be notified when emergency response procedures have been initiated.

3. The Emergency Operations Plan describes how the laboratory will notify external authorities that emergency response measures have been initiated.

14. The laboratory establishes backup communication systems or technologies for use in the event that internal or external systems fail during an emergency.

17. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to support communications during an emergency.
Note: Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.

Standard EM.02.02.03

As part of its Emergency Operations Plan, the laboratory prepares for how it will manage resources and assets during emergencies.

Rationale for EM.02.02.03

The laboratory that continues to provide laboratory services during emergencies needs to determine how resources and assets (that is, supplies, equipment, and facilities) will be managed internally and, when necessary, solicited and acquired from external sources such as vendors, neighboring health care providers, other community organizations, state affiliates, or a regional parent company. The laboratory should also recognize the risk that some resources may not be available from planned sources, particularly in emergencies of long duration or broad geographic scope. This situation may occur when multiple laboratories are vying for a limited supply from the same vendor.

Elements of Performance for EM.02.02.03

2. **For laboratories that plan to provide service during an emergency:** The Emergency Operations Plan describes how the laboratory will obtain and replenish laboratory reagents and related supplies (for example, testing media and plates) that will be required throughout the response and recovery phases of an emergency.

3. **For laboratories that plan to provide service during an emergency:** The Emergency Operations Plan describes how the laboratory will obtain and replenish nonmedical supplies (for example, batteries, soap, towels) that will be required throughout the response and recovery phases of an emergency.

11. The Emergency Operations Plan provides processes for managing space and equipment.

12. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to provide for resources and assets during an emergency. *(See also EM.02.02.11, EP 1)*

Note: Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.
Introduction to Standard EM.02.02.05
Controlling the movement of individuals into, throughout, and out of the laboratory during an emergency is essential to the preservation of the security of patients, staff, and critical supplies, equipment, and utilities. The laboratory determines the type of access and movement to be allowed by staff, patients, visitors, emergency volunteers, vendors, maintenance and repair workers, utility suppliers, and other individuals when emergency measures are initiated. Factors influencing access and movement vary depending on the type of emergency and local conditions (for example, a laboratory may be located within a hospital that has decided to shelter staff members’ families or form mutual aid agreements with nearby facilities or vendors).

Standard EM.02.02.05
As part of its Emergency Operations Plan, the laboratory prepares for how it will manage security during an emergency.

Elements of Performance for EM.02.02.05
1. The Emergency Operations Plan describes how security will be provided during an emergency.
10. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to support internal security during an emergency.

Note: Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.

Standard EM.02.02.07
As part of its Emergency Operations Plan, the laboratory prepares for how it will manage staff during an emergency.

Rationale for EM.02.02.07
In order to provide safe and effective laboratory services during an emergency, staff roles are well defined in advance. Staff roles and responsibilities may be documented in the Emergency Operations Plan through a variety of formats (for example, job action sheets, checklists, flowcharts). Due to the dynamic nature of emergencies, effective training prepares staff to adjust to changes in test volume, work procedures or conditions, and response partners within and outside the organization.
Elements of Performance for EM.02.02.07

The Emergency Operations Plan describes the following:

2. The roles and responsibilities of staff during an emergency.

3. The process for assigning staff to all essential staff functions.

4. The Emergency Operations Plan identifies the individual(s) to whom staff report in emergencies.

10. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to manage staff during an emergency.

Note: Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.

Standard EM.02.02.09

As part of its Emergency Operations Plan, the laboratory prepares for how it will manage utilities during an emergency.

Rationale for EM.02.02.09

Different types of emergencies can similarly impact a laboratory’s utility systems. For example, brush fires, ice storms, and industrial accidents can all result in a loss of utilities required for laboratory services and building operations. Laboratories, therefore, must have alternative means of providing for essential utilities (for example, alternative equipment for laboratory services; negotiated relationships with the primary suppliers; provision through a parent entity; a memorandum of understanding with other organizations in the community). Because some emergencies may be regional in scope or of long duration, organizations should not rely solely on a single utility provider in the community. Where possible, organizations should identify other utility providers outside of the local community in case the community’s infrastructure is severely compromised and unable to support the organization.

Elements of Performance for EM.02.02.09

1. The Emergency Operations Plan describes how the laboratory will provide for alternative means of meeting essential building utility needs when the laboratory needs to provide continuous service during an emergency.

Note: Examples of utility needs include electricity, water, fuel, and medical gas/vacuum systems.
8. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to provide for utilities during an emergency.

**Note:** Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.

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**Standard EM.02.02.11**

As part of its Emergency Operations Plan, the laboratory prepares for how it will manage patients and laboratory services during emergencies.

**Rationale for EM.02.02.11**

The fundamental goals of emergency management planning are to protect life and prevent disability. The manner in which laboratory services are provided may vary by type of emergency. However, certain activities are so fundamental to patient safety (this can include decisions to modify or discontinue laboratory services, refer patients elsewhere, or transport specimens) that the laboratory should take a proactive approach in considering how they might be accomplished.

Emergencies of differing scale, scope, and complexity will impact the laboratory’s operations in different ways, as dictated by the emergency needs of patients. The emergency triage processes will typically result in patients being quickly treated and discharged, admitted for a longer stay, or transferred to a more appropriate source of care. A disaster may result in a decision to keep all patients on the premises in the interest of safety or, conversely, evacuate all patients because the facility is no longer safe. Planning for laboratory services must address these situations accordingly, particularly in the face of escalating events or in potentially austere care conditions.

**Elements of Performance for EM.02.02.11**

1. The Emergency Operations Plan describes how the laboratory will manage services during an emergency. *(See also EM.02.02.03, EP 12)*

**Note:** Activities related to laboratory services might include scheduling, modifying, or discontinuing services; controlling information about patients; referring specimens or testing to other facilities; and providing security. Laboratories may need to do testing for hospital inpatients and ambulatory patients, or as a public health function.
3. The Emergency Operations Plan describes how the laboratory will evacuate its staff and equipment from its occupied space (that is, relocate from one section or floor to another within the building, or completely outside the building) when deemed necessary by emergency circumstances.

9. The Emergency Operations Plan establishes processes for providing backup services, if necessary.

11. The laboratory implements the components of its Emergency Operations Plan that require advance preparation to manage patients during an emergency.

Note: Some components of the Emergency Operations Plan are not implemented unless an emergency is imminent. Other components, however, can and should be implemented in advance so that the laboratory is as prepared as possible.

Introduction to Standard EM.02.02.15

When the Emergency Operations Plan is activated in response to an emergency that escalates to the level of a disaster, and the immediate needs of its patients cannot be met, the laboratory may choose to rely on volunteer practitioners to meet these needs. While this standard allows for a method to streamline the process for determining qualifications and competence, safeguards must be in place to assure that the volunteer practitioners are competent to provide safe and adequate laboratory services. Even in a disaster, the integrity of two specific parts of the usual process for determining qualifications and competence must be maintained:

1. Verification of licensure, certification, or registration required to practice a profession
2. Oversight of the care, treatment, and services provided

A number of state and federal systems engaged in pre-event verification of qualifications can help facilitate the assigning of disaster responsibilities to volunteer practitioners at the time of a disaster. Examples of such systems include the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and the Medical Reserve Corps (MRC). The ESAR-VHP allows for the advance registration and credentialing of health care professionals needed to augment a health care organization to meet increased patient/victim care and increased surge capacity needs. MRC units are
Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing

comprised of locally based medical and public health volunteers who can assist their communities during emergencies, such as an influenza epidemic, a chemical spill, or an act of terrorism.

**Standard EM.02.02.15**

During disasters, the laboratory may assign disaster responsibilities to volunteer practitioners who are not licensed independent practitioners, but who are required by law and regulation to have a license, certification, or registration.

**Note:** While this standard allows for a method to streamline the process for verifying identification and licensure, certification, or registration, the elements of performance are intended to safeguard against inadequate care during a disaster.

**Elements of Performance for EM.02.02.15**

1. The laboratory assigns disaster responsibilities to volunteer practitioners who are not licensed independent practitioners only when the Emergency Operations Plan has been activated in response to a disaster and the laboratory is unable to meet immediate patient needs.

2. The laboratory identifies, in writing, those individuals responsible for assigning disaster responsibilities to volunteer practitioners who are not licensed independent practitioners.

3. The laboratory determines how it will distinguish volunteer practitioners who are not licensed independent practitioners from its staff.

   **Note:** This distinction could be made by using badges, vests, wristbands, or other articles.

4. The laboratory describes, in writing, how it will oversee the performance of volunteer practitioners who are not licensed independent practitioners who have been assigned disaster responsibilities. Examples of methods for overseeing their performance include direct observation, mentoring, and clinical record review.

5. Before a volunteer practitioner who is not a licensed independent practitioner is considered eligible to function as a practitioner, the laboratory obtains his or her valid government-issued photo identification (for example, a driver’s license or passport) and one of the following:
   - A current picture identification card from a health care organization that clearly identifies professional designation
   - A current license, certification, or registration
Primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice)

Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT), the Medical Reserve Corps (MRC), the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), or other recognized state or federal response organization or group

Identification indicating that the individual has been granted authority by a government entity to provide laboratory services in disaster circumstances

Confirmation by laboratory staff with personal knowledge of the volunteer practitioner’s ability to act as a qualified practitioner during a disaster

6. During a disaster, the laboratory oversees the performance of each volunteer practitioner who is not a licensed independent practitioner.

7. Based on its oversight of each volunteer practitioner who is not a licensed independent practitioner, the laboratory determines within 72 hours after the practitioner’s arrival whether assigned disaster responsibilities should continue.

8. Primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) of volunteer practitioners who are not licensed independent practitioners occurs as soon as the disaster is under control or within 72 hours from the time the volunteer practitioner presents him- or herself to the laboratory, whichever comes first. If primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) for a volunteer practitioner who is not a licensed independent practitioner cannot be completed within 72 hours due to extraordinary circumstances, the laboratory documents all of the following:

   - Reason(s) why it could not be performed within 72 hours of the practitioner’s arrival
   - Evidence of the volunteer practitioner’s demonstrated ability to continue to provide adequate laboratory services
   - Evidence of the laboratory’s attempt to perform primary source verification as soon as possible

9. If, due to extraordinary circumstances, primary source verification of licensure of the volunteer practitioner cannot be completed within 72 hours of the practitioner’s arrival, it is performed as soon as possible.
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Note: Primary source verification of licensure, certification, or registration is not required if the volunteer practitioner has not provided laboratory services under his or her assigned disaster responsibilities.

Standard EM.03.01.03
The laboratory evaluates the effectiveness of its Emergency Operations Plan.

Rationale for EM.03.01.03
The laboratory conducts exercises to assess the Emergency Operations Plan’s (EOP) appropriateness, adequacy, and effectiveness in the areas of communications, resources and assets, security, staff, and utilities. Exercises should test the EOP’s ability to support the laboratory’s preparedness and performance in a variety of possible emergencies. In other words, the design of the exercises should reflect differing degrees of emergencies while testing the organization’s capability to provide laboratory services in escalating situations.

Elements of Performance for EM.03.01.03

1. As an emergency response exercise, the laboratory activates its Emergency Operations Plan twice a year at each site included in the plan; laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) are required to activate the plan only once each year.

   Note 1: If the organization activates its Emergency Operations Plan in response to one or more actual emergencies, these emergencies can serve in place of emergency response exercises.

   Note 2: Tabletop sessions, though useful, are not acceptable substitutes for these exercises.

   Note 3: If the laboratory is part of a Joint Commission–accredited organization, the frequency of the emergency response exercise is based on the organizational plan. Because most laboratories accredited by The Joint Commission are in hospitals, they will follow the hospital requirement for two tests.

13. Representatives from administrative, support, and laboratory services participate in the evaluation of all emergency response exercises and all responses to actual emergencies.
14. The evaluation of all emergency response exercises and all responses to actual
emergencies includes the identification of deficiencies and opportunities for
improvement. This evaluation is documented.

16. The laboratory modifies its Emergency Operations Plan based on its evaluation of
emergency response exercises and responses to actual emergencies.

    Note: When modifications requiring substantive resources cannot be accomplished by
the next emergency response exercise, interim measures are put in place until final
modifications can be made.

17. Subsequent emergency response exercises reflect modifications and interim
measures as described in the modified Emergency Operations Plan.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

What are ALL the potential emergencies that may disrupt the laboratory’s ability to provide services? (EM.01.01.01)

Can each staff member who has a role in mitigation, preparedness, response, or recovery activities describe his or her assigned responsibilities? (EM.01.01.01)

Has the Emergency Operations Plan (EOP) been updated to include response procedures and opportunities for improvement when responding to each emergency situation? (EM.02.01.01)

**TIP:** Review with your staff your current EOP, description of your planned exercises, and responses to emergencies.

How will the laboratory notify patients, staff, independent practitioners (such as pathologists), and authorities when emergency response procedures have been initiated? (EM.02.02.01)
TIP: Verify that the laboratory’s EOP addresses management of the following during emergency:
- Resources and assets needed for laboratory operation
- Laboratory equipment and instruments
- Security and safety of patients and staff
- Utilities such as electricity, water, and vacuum systems
**Written Documentation Checklist**
This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
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| | EM.02.01.01, EP 2 | The laboratory has a written Emergency Operations Plan that describes the response procedures to follow when emergencies occur. **Note:** The response procedures address the prioritized emergencies but can also be adapted to other emergencies that the laboratory may experience. Response procedures could include the following:  
  - Maintaining or expanding services  
  - Conserving resources  
  - Curtailing services  
  - Relocating services to an alternative site  
  - Supplementing resources from outside the local community  
  - Closing the laboratory to new patients  
  - Staged evacuation  
  - Total evacuation | |
| | EM.02.01.01, EP 4 | The laboratory has a written Emergency Operations Plan that describes the recovery strategies, actions, and individual responsibilities necessary to restore the laboratory's services after an emergency. | |
| | EM.02.02.15, EP 2 | The laboratory identifies, in writing, those individuals responsible for assigning disaster responsibilities to volunteer practitioners who are not licensed independent practitioners. | |
| | EM.02.02.15, EP 4 | The laboratory describes, in writing, how it will oversee the performance of volunteer practitioners who are not licensed independent practitioners who have been assigned disaster responsibilities. Examples of methods for overseeing their performance include direct observation, mentoring, and clinical record review. | |
| EM.02.02.15, EP 8 | Primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) of volunteer practitioners who are not licensed independent practitioners occurs as soon as the disaster is under control or within 72 hours from the time the volunteer practitioner presents him- or herself to the laboratory, whichever comes first. If primary source verification of licensure, certification, or registration (if required by law and regulation in order to practice) for a volunteer practitioner who is not a licensed independent practitioner cannot be completed within 72 hours due to extraordinary circumstances, the laboratory documents all of the following:

- Reason(s) why it could not be performed within 72 hours of the practitioner's arrival
- Evidence of the volunteer practitioner’s demonstrated ability to continue to provide adequate laboratory services
- Evidence of the laboratory’s attempt to perform primary source verification as soon as possible |
| EM.03.01.03, EP 14 | The evaluation of all emergency response exercises and all responses to actual emergencies includes the identification of deficiencies and opportunities for improvement. This evaluation is documented. |
**Action Planning Tool**

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Human Resources (HR)

Overview
The contribution that human resources management makes to a laboratory’s ability to provide safe, quality services cannot be overestimated. The quality of the laboratory’s staff will, in large part, determine the quality of laboratory services provided to patients. The World Health Report 2000—Health Systems: Improving Performance states that human resources is the most important contribution to the quality of health care because “the performance of health care systems depends ultimately on the knowledge, skills, and motivation of the people responsible for delivering services.”

This same report describes staff education and training as key investment tools: “Unlike material capital, knowledge does not deteriorate with use. But, like equipment, old skills become obsolete with the advent of new technologies. Continuing education and on-the-job training are required to keep existing skills in line with technological progress and new knowledge.” After staff are hired, even the smallest laboratory has a responsibility to see that they receive the education and training they need to provide quality services.

About This Chapter
The standards and elements of performance in this chapter address the laboratory’s responsibility to establish and verify staff qualifications, orient staff, and provide staff with the training they need to provide services. After staff are on the job, human resources must provide for the assessment of staff competence and performance. These requirements apply to all individuals serving in the personnel roles defined for nonwaived testing in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). For laboratories performing moderate-complexity testing, this specifically includes the roles of laboratory director, technical consultant, clinical consultant, and testing personnel. For laboratories performing high-complexity testing, the roles include laboratory director, technical supervisor, clinical consultant, general supervisor, and testing personnel.

Note: Laboratory staff qualifications are determined by the laboratory director. These requirements can be found in the “Leadership” (LD) chapter, LD.04.05.03.
Chapter Outline

I.  Staff
   A. Qualifications (HR.01.01.01, HR.01.02.03, HR.01.02.07)
   B. Staffing (HR.01.02.05)
   C. Supervision (HR.01.03.01)
   D. Orientation (HR.01.04.01)
   E. Training and Education (HR.01.05.03)
   F. Competence (HR.01.06.01)
   G. Evaluation of Performance (HR.01.07.01)

II. Licensed Independent Practitioners—Not applicable to laboratories

III. Primary Care Medical Home—Not applicable to laboratories
Standards, Rationales, and Elements of Performance

Standard HR.01.01.01
The laboratory verifies staff qualifications.

Elements of Performance for HR.01.01.01

2. The laboratory verifies and documents the following:
   - Credentials of laboratory service providers using the primary source when licensure, certification, or registration is required by law and regulation to practice their profession. This is done at the time of hire and at the time credentials are renewed.
   - Credentials of laboratory service providers (primary source not required) when licensure, certification, or registration is not required by law and regulation. This is done at the time of hire and at the time credentials are renewed.

   **Note 1:** It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.

   **Note 2:** A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.

   **Note 3:** An external organization (for example, a credentials verification organization [CVO]) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

3. The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities.


6. The laboratory uses the following information to make decisions about staff job responsibilities:
   - Verified licensure, certification, or registration required by law or regulation or the laboratory
Verified education and experience

**Standard HR.01.02.03**

One or more qualified professionals direct pathology and clinical laboratory services.

**Elements of Performance for HR.01.02.03**

1. The qualifications of the laboratory director\(^1\) of record meet the requirements set forth in federal and state law and regulation. (See also QSA.03.01.01, EP 1) \(\text{R}\)

2. The laboratory director possesses effective management skills.

   **Note:** An example of effective management is the ability of the laboratory director to delegate responsibility to others in the department or laboratory who have the qualifications to perform those responsibilities. (See also LD.04.05.01, EP 7)

3. A qualified individual\(^2\) provides clinical consultation. \(\text{R}\)

   **Note:** In hospitals, it is preferable to have a pathologist providing clinical consultation.

4. A qualified individual\(^3\) directs clinical laboratory services. \(\text{R}\)

5. A pathologist directs anatomic pathology services. \(\text{R}\)

6. A pathologist or another physician qualified in cytology directs cytology services. \(\text{R}\)

7. A pathologist or another physician qualified in immunohematology, hemotherapy, and blood banking directs blood-transfusion services. (See also LD.04.05.01, EP 7) \(\text{R}\)

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8. A pathologist, doctoral scientist, or other qualified physician with specialized training or experience in molecular pathology directs molecular pathology services.

9. A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:
   - A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation
   - Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.

Note: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.

Introduction to Standard HR.01.02.05
According to Subpart M of the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), the required personnel positions for nonwaived testing are as follows:
   - Laboratory director, technical consultant, clinical consultant, and testing personnel for moderate-complexity testing
   - Laboratory director, technical supervisor, clinical consultant, general supervisor, and testing personnel for high-complexity testing

A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.

Standard HR.01.02.05
The laboratory has the necessary staff to support the services it provides.
Element of Performance for HR.01.02.05

1. An individual qualified to provide technical consultation or supervision and general supervision\(\text{II}\) is on duty or is available whenever testing requires consultation or supervision. \(\text{R}\)

   Note: This individual can be available on site, by telephone, or by electronic consultation.

Standard HR.01.02.07
The laboratory determines how staff function within the organization.

Elements of Performance for HR.01.02.07

1. All staff who provide laboratory services possess a current license, certification, or registration, in accordance with law and regulation.

2. Staff who provide laboratory services practice within the scope of their license, certification, or registration and as required by law and regulation.

5. Staff supervise and observe students when they are performing laboratory procedures.

Standard HR.01.03.01
Staff are supervised effectively.

Element of Performance for HR.01.03.01

3. Supervisory staff have training and experience to supervise.

Standard HR.01.04.01
The laboratory provides orientation to staff.

Elements of Performance for HR.01.04.01

1. \(\text{G}\) The laboratory orients its staff to the key safety content it identifies before staff provides laboratory services. Completion of this orientation is documented.

   Note: Key safety content may include specific processes and procedures related to the provision of laboratory services, the environment of care, and infection control.

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\(\text{II}\) Qualifications to provide technical consultation or supervision and general supervision are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) under Subpart M: “Personnel for Nonwaived Testing,” §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.
3. ☐ The laboratory orients staff on the following:

- Organizationwide and laboratory-specific policies and procedures related to job duties and responsibilities
- Their specific job duties and responsibilities, including those related to infection prevention and control
- Sensitivity to cultural diversity based on their job duties and responsibilities
- Patient rights, including ethical aspects of laboratory services and the process used to address ethical issues based on their job duties and responsibilities

Completion of this orientation is documented.

9. Staff are oriented to each preanalytic, analytic, and postanalytic activity they will be expected to perform.

**Note 1:** Preanalytic activity includes patient identification and preparation; specimen collection, labeling, handling, processing or preparation, preservation, and fixation; transportation and storage; instrument preventive maintenance, troubleshooting and calibration procedures; and quality control and documentation of all quality control activities, including instrument and procedural calibrations and maintenance.

**Note 2:** Analytic activity includes test performance and knowledge of reagent stability and storage.

**Note 3:** Postanalytic activity includes results reporting (including assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results), identifying factors that may adversely affect test performance, correcting identified problems, or notifying the supervisor when problems arise.

10. ☐ Prior to performing laboratory duties, the following are completed:

- The laboratory director or supervisor documents that staff have completed orientation and have demonstrated competence in performing their required duties.
- The staff member affirms, in writing, that he or she can perform the duties for which orientation was provided.

**Standard HR.01.05.03**
Staff participate in education and training.
Elements of Performance for HR.01.05.03

1. 🟣 Staff participate in education and training to maintain or increase their competency and whenever staff responsibilities change, including when a test, methodology, or instrumentation changes. Staff participation is documented. R

5. 🟣 Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. R

Introduction to Standard HR.01.06.01

All staff who perform high, moderate, and provider-performed microscopy (PPM) procedures testing, including supervisors, physicians, dentists, and midlevel practitioners, participate in competence demonstrations as described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) under Subpart M: “Personnel for Nonwaived Testing,” §493.1413(8) and §493.1451(8). A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.

Standard HR.01.06.01

Staff are competent to perform their responsibilities.

Elements of Performance for HR.01.06.01

3. An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence. R

5. 🟣 Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is initially assessed and documented as part of orientation.

6. 🟣 Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is assessed and documented once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation.

15. The laboratory takes action when a staff member’s competence does not meet expectations.

18. The staff member’s competency assessment includes the following:
   - Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing
   - Monitoring, recording, and reporting of test results
   - Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance
   - Direct observation of performance of instrument maintenance function checks and calibration
   - Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)
   - Problem-solving skills as appropriate to the job

   (See also WT.03.01.01, EP 6)

19. During the first year of employment, each staff member’s competence is assessed at least semiannually for all laboratory tests he or she performs. This assessment is documented.

   Note: For waived testing competency requirements, refer to the “Waived Testing” (WT) chapter.

20. After the first year of employment, each staff member’s competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.

   Note: For waived testing competency requirements, refer to the “Waived Testing” (WT) chapter.

21. If a test, methodology, or instrumentation changes, or the individual’s duties change, his or her competence to perform these new skills or duties is assessed. This assessment is documented.

22. For histocompatibility testing, the competency assessment process includes the following:
   - A defined system to confirm testing competence
- A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly
- Established acceptable performance criteria
- Documented performance levels
- Documented corrective action

**Standard HR.01.07.01**

The laboratory evaluates staff performance.

**Elements of Performance for HR.01.07.01**

1. The laboratory evaluates staff based on performance expectations that reflect their job responsibilities.

2. The laboratory evaluates staff performance once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation. This evaluation is documented.

5. When an employee brings a nonemployee individual into the laboratory to provide care, treatment, and services (for example, when a pathologist brings a pathology assistant into the laboratory to assist with histology specimen processing), the laboratory reviews the individual’s competencies and performance at the same frequency as individuals employed by the hospital.

**Note:** This review can be accomplished either through the laboratory’s regular process or with the employee who brought staff into the hospital.
Prompts to Assess Your Compliance

**Please note:** Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

How does the laboratory verify qualifications of the laboratory director and all laboratory personnel? (HR.01.02.03, HR.01.02.05)

**TIP:** Understand CLIA requirements for all types of laboratory personnel.
- Required roles for **High Complexity Testing**: Laboratory Director, Clinical Consultant, Technical Supervisor (per specialty/subspecialty), General Supervisor, and Testing Personnel
- **Technical Supervisor** may have additional requirements: cytology, clinical cytogenetics, histocompatibility, histopathology – general, dermatopathology, ophthalmic pathology, oral pathology, and immunohematology
- Required roles for **Moderate Complexity Testing**: Laboratory Director, Clinical Consultant, Technical Consultant (per specialty/subspecialty), Testing Personnel
- **Technical Consultant** minimum requirement is a 4-year degree and 2 years experience in the specialty. Blood gases may need someone from the laboratory to fill this role.

Have all licenses and certifications been checked with primary resources on hire and prior to expiration? (HR.01.02.05)

**TIP:** Primary source verification is not required unless the license or certification is required by law or regulation.
**TIP:** Review policy on using primary source verification (PSV). See Standards FAQ on The Joint Commission’s Laboratory Accreditation web page.

How does the laboratory verify the highest level of education? (HR.01.02.05)

**TIP:** Some US states have different requirements for laboratory personnel. Review your specific state’s requirements for laboratory personnel.

Have all new hires completed orientation? Are initial training and repeating competencies up to date for all staff, and does competency training meet the requirements for each laboratory specialty? (HR.01.04.01)

**TIP:** Work with the organization’s human resources department. The laboratory requirement is different from the hospital requirement.

Are all laboratory staff aware of their job responsibilities? (HR.01.04.01)
Have performance evaluations been completed within the time frames defined by the laboratory policy and The Joint Commission standards? (HR.01.07.01)

Are the appropriate laboratory staff members conducting competencies for the appropriate skill classifications? (HR.01.06.01)

**TIP:** Ensure a qualified person does the assessment.

- **High Complexity:** Technical Supervisor or General Supervisor. General Supervisor responsibility must be delegated in writing from the Technical Supervisor.
- **Moderate Complexity:** Technical Consultant. Technical Consultant responsibilities may not be delegated.

What are the methods for reviewing staff competencies and how frequently are they performed? Does the frequency meet the time frame requirements per testing complexities? (HR.01.06.01)

**TIP:** Verify that first-year hires have assessment scheduled at six months. Have two years’ documentation of competency assessment available during survey. Consider incorporating review of responsibilities into annual employee evaluations.

What are the competency requirements for personnel performing microscopy? (HR.01.06.01)
TIP: Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived Testing and PPM Note: PPM are not waived tests</th>
<th>Waived Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Use 6 methods (if applicable)</td>
<td>Use 2 of 4 methods</td>
</tr>
<tr>
<td></td>
<td>1. Blind testing</td>
<td>1. Blind testing</td>
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<tr>
<td></td>
<td>2. Direct observation of routine testing</td>
<td>2. Direct observation of routine testing</td>
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<td></td>
<td>3. Monitoring of QC performance by each user</td>
<td>3. Monitoring of QC performance by each user</td>
</tr>
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<td></td>
<td>4. Problem solving skills</td>
<td>4. Written test</td>
</tr>
<tr>
<td></td>
<td>5. Direct observation of instrument checks</td>
<td></td>
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<tr>
<td></td>
<td>6. Monitoring result reporting</td>
<td></td>
</tr>
<tr>
<td>Initial Training and Annual Assessment</td>
<td>Yes Semi-annual in the first year</td>
<td>Yes</td>
</tr>
<tr>
<td>Signatures</td>
<td>Both the director/supervisor/consultant AND the employee must sign that the individual has received training and is competent prior to performing testing independently.</td>
<td>No signature required but the director/designee must assess competency</td>
</tr>
</tbody>
</table>

What is the process to maintain credentialing records for licensed laboratory personnel if licenses are required by law and regulation? (HR.01.02.07)

TIP: Develop a systematic process for auditing human resources records. Include a method for “flagging” items that are missing or that must be addressed at a specified deadline.
**Written Documentation Checklist**

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
</tr>
</thead>
</table>
|   | HR.01.01.01, EP 2 | The laboratory verifies and documents the following:  
- Credentials of laboratory service providers using the primary source when licensure, certification, or registration is required by law and regulation to practice their profession. This is done at the time of hire and at the time credentials are renewed.  
- Credentials of laboratory service providers (primary source not required) when licensure, certification, or registration is not required by law and regulation. This is done at the time of hire and at the time credentials are renewed.  
**Note 1:** It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.  
**Note 2:** A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.  
**Note 3:** An external organization (for example, a credentials verification organization [CVO]) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary. | |
<p>|   | HR.01.01.01, EP 3 | The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities. Note: Education and experience requirements are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: &quot;Personnel for Nonwaived Testing,&quot; §493.1351 - §493.1495. A complete description of the requirement is located at <a href="http://wwwn.cdc.gov/clia/Regulatory">http://wwwn.cdc.gov/clia/Regulatory</a>. | |</p>
<table>
<thead>
<tr>
<th>Standard</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR.01.04.01, EP 1</td>
<td>The laboratory orients its staff to the key safety content it identifies before staff provides laboratory services. Completion of this orientation is documented. <strong>Note:</strong> Key safety content may include specific processes and procedures related to the provision of laboratory services, the environment of care, and infection control.</td>
</tr>
</tbody>
</table>
| HR.01.04.01, EP 3 | The laboratory orients staff on the following:  
- Organizationwide and laboratory-specific policies and procedures related to job duties and responsibilities.  
- Their specific job duties and responsibilities, including those related to infection prevention and control.  
- Sensitivity to cultural diversity based on their job duties and responsibilities.  
- Patient rights, including ethical aspects of laboratory services and the process used to address ethical issues based on their job duties and responsibilities.  
Completion of this orientation is documented. |
| HR.01.04.01, EP 10 | Prior to performing laboratory duties, the following are completed:  
- The laboratory director or supervisor documents that staff have completed orientation and have demonstrated competence in performing their required duties.  
- The staff member affirms, in writing, that he or she can perform the duties for which orientation was provided. |
| HR.01.05.03, EP 1 | Staff participate in education and training to maintain or increase their competency and whenever staff responsibilities change, including when a test, methodology, or instrumentation changes. Staff participation is documented. |
| HR.01.05.03, EP 5 | Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented. |
| HR.01.06.01, EP 5 | Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is initially assessed and documented as part of orientation. |
| HR.01.06.01, EP 6 | Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is assessed and documented once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation. |
| HR.01.06.01, EP 18 | The staff member's competency assessment includes the following:  
- Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing  
- Monitoring, recording, and reporting of test results  
- Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance  
- Direct observation of performance of instrument maintenance function checks and calibration  
- Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)  
- Problem-solving skills as appropriate to the job (See also WT.03.01.01, EP 6) |
| HR.01.06.01, EP 19 | During the first year of employment, each staff member's competence is assessed at least semiannually for all laboratory tests he or she performs. This assessment is documented.  
**Note:** For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter. |
| HR.01.06.01, EP 20 | After the first year of employment, each staff member’s competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.  
**Note:** For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter. |
| HR.01.06.01, EP 21 | If a test, methodology, or instrumentation changes, or the individual's duties change, his or her competence to perform these new skills or duties is assessed. This assessment is documented. |
| HR.01.07.01, EP 2 | The laboratory evaluates staff performance once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation. This evaluation is documented. |
**Action Planning Tool**

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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<tbody>
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</table>
Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Infection Prevention and Control (IC)

Overview
The Centers for Disease Control and Prevention (CDC) reports that 1.7 million infections annually are health care related, and as a result, 99,000 people will die each year. Health care practitioners in the organization know all too well about health care–associated infections. Contemporary health care, despite its great strides in preventing and treating disease, has yet to conquer the risk of patients acquiring an infection in the very place where infection should be least present. Multidrug-resistant infections can be acquired in almost any setting, making the need for effective support for infection prevention and control in the organization all the more important.

The design and scope of the organization’s infection prevention and control program are determined by the specific risks faced by its location, the population it serves, and the types of services it provides. An effective program includes activities that are up-to-date and routinely performed. If the laboratory is part of an accredited organization that meets the requirements of this chapter, the laboratory is not required to create a separate program but can rely on the organization’s infection prevention and control program to guide its activities. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting all requirements in this chapter and will need to assess infection risks and plan and implement interventions independently. When an effective program is in place, the organization takes measures so that the program operates consistently and is evaluated to identify improvement opportunities.

Effective infection prevention and control plans have the input and support of organization leadership and will emphasize communication and collaboration. Everyone involved in the daily operations of the laboratory, from medical technologists to phlebotomists to clerical staff, should play a role. For example, phlebotomists should take precautions to prevent germs from passing from patient to patient; staff who receive

patients should take measures (including respiratory etiquette) to prevent the spread of disease from staff to pens or pencils to patient and back again; everyone should incorporate hand hygiene protocols. Staff should be supported in taking responsibility for their self-care when they know or suspect they have an infection. Clearly, all laboratory staff need to observe proper infection prevention and control techniques at all times.

About This Chapter
The processes outlined in the “Infection Prevention and Control” (IC) chapter are applicable to all infections or potential sources of infection that laboratory staff might encounter, including a sudden influx of potentially infectious patients or patient specimens. The standards are designed to assist organizations, both large and small, in developing and maintaining an effective program that covers a wide range of situations. These standards address activities of planning, implementation, and evaluation and are based on the following conditions necessary to establish and operate an effective infection prevention and control program. Every laboratory, regardless of its size or the services it provides, should do the following:

- Recognize that its infection prevention and control program plays a major role in its efforts to improve patient safety and quality of care
- Demonstrate leadership’s commitment to infection prevention and control by endorsing and participating in the laboratory’s efforts to control infection, provide resources, and encourage improvement
- See that staff collaborate with each other when designing and implementing the infection prevention and control program
- Regularly assess its infection prevention and control program by using an epidemiological approach that consists of surveillance, data collection, analysis, and trend identification
- Coordinate its program with the larger community
- Take into account that the potential exists for an infection outbreak so extensive that it overwhelms the laboratory’s resources
Chapter Outline

I. Planning
   A. Responsibility (IC.01.01.01)
   B. Resources (IC.01.02.01)
   C. Risks (IC.01.03.01)
   D. Goals (IC.01.04.01)
   E. Activities (IC.01.05.01)
   F. Influx (IC.01.06.01)

II. Implementation
   A. Activities (IC.02.01.01)
   B. Laboratory Equipment, Devices, and Supplies (IC.02.02.01)
   C. Transmission of Infectious Disease (IC.02.03.01)
   D. Influenza Vaccinations (IC.02.04.01)

III. Evaluation and Improvement (IC.03.01.01)
Introduction to Standards IC.01.01.01 Through IC.01.06.01 – Planning

For any infection prevention and control program to be effective, it needs to be well managed. Toward that end, laboratory leadership assigns one or more laboratory staff to be responsible for development and management of the program. Depending on the size of the laboratory and its resources, and whether it is an independent organization (not owned by or affiliated with a health care organization, such as a reference laboratory) or part of an accredited organization, this individual(s) can be an employee, a contractor, or a consultant. After an individual(s) is assigned, the work of planning the infection prevention and control program can begin by gathering staff with expertise in infection control, building management staff, and other key team members who can perform a risk assessment and establish infection prevention and control activities.

Those responsible for managing infection prevention and control may want to consult with community leaders and other outside infection control experts who can provide important information about the organization’s population served and associated health risks. Understanding the likelihood of an influx of infectious patients or patient specimens is a valuable component of this planning process.

The results of the laboratory’s infection risk assessment should be prioritized, ideally in order of level of probability and potential for harm. The laboratory can then set goals for reducing the risks of the infections that pose the most threat to patients, staff, and the community. These goals should lead to focused activities, based on relevant professional guidelines and sound scientific practices.

Standard IC.01.01.01

The laboratory identifies the individual(s) responsible for managing infection prevention and control for laboratory services.
Rationale for IC.01.01.01
The infection prevention and control program requires management by an individual (or individuals) with knowledge that is appropriate to the level of identified risks, as well as knowledge of the analysis of infection risks, principles of infection prevention and control, and data analysis. The individual(s) may be employed or under contract. The laboratory’s size, complexity, and structure (laboratories that are independent organizations, not owned by or affiliated with a health care organization, such as reference laboratories) may influence the number of individuals required and their qualifications in infection prevention and control.

Element of Performance for IC.01.01.01
3. Laboratory leaders assign responsibility for the management of infection prevention and control activities for laboratory services. (See also LD.04.05.03, EP 1)

Note: Number and skill mix of the individual(s) assigned should be determined by the goals and objectives of the infection prevention and control program.

Standard IC.01.02.01
Laboratory leaders designate laboratory resources needed to support the organization-wide infection prevention and control activities.

Elements of Performance for IC.01.02.01
1. The laboratory provides access to laboratory-related information needed to support the organization-wide infection prevention and control program. (See also IM.02.02.03, EP 2)
3. The laboratory provides equipment and supplies for the laboratory services needed to support the organization-wide infection prevention and control program.

Standard IC.01.03.01
The laboratory identifies its risks for acquiring and transmitting infections.

Elements of Performance for IC.01.03.01
1. The laboratory identifies its infection risks based on the laboratory services it provides.
3. The laboratory prioritizes its identified risks for acquiring and transmitting infections. These prioritized risks are documented.
Standard IC.01.04.01

Based on its identified risks, the laboratory sets goals to minimize the possibility of transmitting infections.

Note: See NPSG.07.01.01 for hand hygiene guidelines.

Element of Performance for IC.01.04.01

1. The laboratory’s written infection prevention and control goals address the following:
   - Its prioritized risks
   - Limiting unprotected exposure to pathogens
   - Limiting the transmission of infections associated with procedures
   - Limiting the transmission of infections associated with the use of laboratory equipment, devices, and supplies
   - Improving compliance with hand hygiene guidelines (See also NPSG.07.01.01, EP 1)

Standard IC.01.05.01

The organization plans for preventing and controlling infections associated with laboratory services.

Elements of Performance for IC.01.05.01

1. When developing its infection prevention and control activities, the laboratory uses evidence-based national guidelines or, in the absence of such guidelines, expert consensus.†

2. The laboratory plans infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection associated with laboratory services. The description of these planned activities is documented.

Note: These infection prevention and control activities may be planned by the laboratory and/or by an affiliated organization that includes the laboratory.

6. All laboratory components and functions are integrated into the organizationwide infection prevention and control activities.

Standard IC.01.06.01
The organization prepares to respond to an increased number of potentially infectious patients or patient specimens.

Rationale for IC.01.06.01
The laboratory is an important resource for the continued functioning of a community. A laboratory’s ability to deliver services is threatened when it is ill-prepared to respond to an epidemic or infections likely to require expanded or extended care capabilities over a prolonged period. Therefore, it is important to quickly recognize that existing patients have become infected, plan how to prevent the introduction of the infection into the laboratory, and contain the risk or spread of the infection.

Elements of Performance for IC.01.06.01

3. The laboratory has a method for communicating critical information to licensed independent practitioners and staff about emerging infections that could cause an increase in the number of infectious patients or patient specimens handled.

4. The laboratory plans how it will respond to an increased number of potentially infectious patients or patient specimens. This plan is documented. (See also EM.01.01.01, EP 2)

Introduction to Standards IC.02.01.01 Through IC.02.03.01 – Implementation
The activities of infection prevention and control should be practical and involve collaboration between departments and staff. Everyone who works in the organization has a role and should hold each other accountable, whether the laboratory is an independent organization (not owned by or affiliated with a health care organization, such as a reference laboratory) or part of an accredited organization. Important infection prevention and control information should be available to laboratory staff, and standard and transmission-based precautions should be used. Any outbreak of infection within the organization should be investigated, and specimen storage and disposal should be handled in a safe manner at all times.

\(^1\) A response plan may include accessing the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) at http://emergency.cdc.gov/lrn/index.asp for information and guidance.
Standard IC.02.01.01
The laboratory implements its infection prevention and control activities.

Elements of Performance for IC.02.01.01

1. The laboratory implements its planned infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.

2. The laboratory uses standard precautions, including the use of personal protective equipment, to reduce the risk of infection. (See also EC.02.02.01, EP 4)
   
   **Note:** Standard precautions are infection prevention and control measures to protect against possible exposure to infectious agents. These precautions are general and applicable to all patients and patient specimens.

3. The laboratory implements transmission-based precautions in response to the pathogens that are suspected or identified within the organization’s service setting and community. (See also EC.02.02.01, EP 3)
   
   **Note:** Transmission-based precautions are infection prevention and control measures to protect against exposure to a suspected or identified pathogen. These precautions are specific and based on the way the pathogen is transmitted. Transmission-based precautions include contact, droplet, airborne, or a combination of these precautions.

4. The laboratory minimizes the risk of infection when storing and disposing of infectious waste. (See also EC.02.02.01, EPs 1 and 12)

5. The laboratory implements its methods to communicate responsibilities for preventing and controlling infection to staff, visitors, and patients.

6. The laboratory reports infection surveillance, prevention, and control information to laboratory staff consistent with their responsibilities for infection prevention and control activities.

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5 For further information regarding standard precautions, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hai/ (Infection Control in Healthcare Settings) and the Occupational Safety and Health Administration’s Blood Borne Pathogen Act at http://www.osha.gov.

6 For further information regarding transmission-based precautions, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hai/ (Infection Control in Healthcare Settings).
9. The laboratory reports or supports the reporting of infection surveillance, prevention, and control information and reportable diseases to local, state, and federal public health authorities, in accordance with law and regulation.

**Standard IC.02.02.01**

The laboratory reduces the risk of infections associated with laboratory equipment, devices, and supplies.

**Rationale for IC.02.02.01**

People are at risk of developing an infection from contact with laboratory equipment, devices, or supplies. Failure to properly clean, disinfect, or sterilize, and use or store, laboratory equipment, devices, and supplies poses the risk for person-to-person transmission of infections.

There are numerous steps involved in the cleaning, disinfecting, and sterilizing of laboratory equipment, devices, and supplies. It is critical that health care workers follow standardized practices to minimize infection risks related to laboratory equipment, devices, and supplies. In order to maintain a reliable system for controlling this process, organizations pay attention to the following:

- Orientation, training, and competency of health care workers who are processing laboratory equipment, devices, and supplies
- Levels of staffing and supervision of the health care workers who are processing laboratory equipment, devices, and supplies
- Standardization of process regardless of whether it is centralized or decentralized
- Reinforcing the process (for example, the use of placards which list the steps to be followed, according to manufacturer’s guidelines)
- Ongoing quality monitoring

**Elements of Performance for IC.02.02.01**

The laboratory implements infection prevention and control activities when doing the following:

1. Cleaning and performing low-level disinfection of laboratory equipment, devices, and supplies.

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*For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html.*
Note: Low-level disinfection is used for items such as blood glucose meters. Additional cleaning and disinfecting is required for laboratory equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions.

2. Performing intermediate and high-level disinfection and sterilization of laboratory equipment, devices, and supplies.” (See also EC.02.04.03, EP 4)

Note: Intermediate-level disinfection may be used in the clean-up of blood and/or body fluid spills. When decontaminating the autopsy room and handing tissues where prion disease is suspected or confirmed, high-level disinfection is often used in combination with sterilization.

3. Disposing of laboratory equipment, devices, and supplies.

4. Storing laboratory equipment, devices, and supplies.

Standard IC.02.03.01
The organization works to prevent the transmission of infectious disease among patients and staff.

Elements of Performance for IC.02.03.01

1. The organization makes screening for exposure and/or immunity to infectious disease available to staff who may come in contact with infections at the workplace. R

2. When staff have, are suspected of having, or have been occupationally exposed to an infectious disease that puts others at risk, the organization provides them with or refers them for assessment and potential testing, prophylaxis/treatment, or counseling. R

For further information regarding performing intermediate and high-level disinfection of laboratory equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html (Sterilization and Disinfection in Healthcare Settings).
**Introduction to Standard IC.02.04.01**

Influenza vaccination for staff and licensed independent practitioners is a major safety issue in the United States. Unvaccinated individuals who become infected are contagious at least one day before any signs or symptoms of influenza appear, and therefore these individuals can infect others without knowing they are contagious. Both government and professional organizations emphasize increasing safety to those receiving health care by decreasing their exposure to the influenza virus while receiving this care. One way to improve patient safety is for staff and licensed independent practitioners to receive the influenza vaccination annually. According to the US Department of Health and Human Services, vaccination is an effective preventive measure against influenza and can prevent many illnesses, deaths, and losses in productivity. Health care personnel (HCP) are considered a high priority for expanding influenza vaccine use. Achieving and sustaining high influenza vaccination coverage among HCP is intended to help protect HCP and their patients and reduce disease burden and health care costs (see [http://www.hhs.gov/ash/initiatives/hai/hcpflu.html](http://www.hhs.gov/ash/initiatives/hai/hcpflu.html)).

The Joint Commission’s Standard IC.02.04.01 reflects current science and the national focus on influenza vaccination. It requires that each organization has an influenza vaccination program and that the influenza vaccination is offered to staff and licensed independent practitioners. However, The Joint Commission does not mandate influenza vaccination for licensed independent practitioners and staff as a condition of Joint Commission accreditation. Additionally, The Joint Commission does not require accredited organizations to pay for the influenza vaccination for its licensed independent practitioners and staff. The decision on whether to pay for the influenza vaccination for staff and licensed independent practitioners will need to be made independently by each accredited organization.

**Standard IC.02.04.01**

The laboratory offers vaccination against influenza to licensed independent practitioners and staff.

**Note 1:** This standard is applicable to staff and licensed independent practitioners only when care, treatment, or services are provided on site. When care, treatment, or services are provided off site, such as with telemedicine or telephone consultation, this standard is not applicable to off-site staff and licensed independent practitioners.

**Note 2:** This standard is only applicable to laboratories that are not included in a hospital’s influenza program for staff and licensed independent practitioners.
Elements of Performance for IC.02.04.01

1. The laboratory establishes an annual influenza vaccination program that is offered to licensed independent practitioners and staff.

2. The laboratory educates licensed independent practitioners and staff about, at a minimum, the influenza vaccine; non-vaccine control and prevention measures; and the diagnosis, transmission, and impact of influenza.

3. The laboratory provides the influenza vaccination at sites and times accessible to licensed independent practitioners and staff.

4. The laboratory includes in its infection control plan the goal of improving influenza vaccination rates. (For more information, refer to Standard IC.01.04.01.)

5. The laboratory sets incremental influenza vaccination goals, consistent with achieving the 90% rate established in the national influenza initiatives for 2020.


6. The laboratory has a written description of the methodology used to determine influenza vaccination rates.

   Note: The National Quality Forum (NQF) Measure Submission and Evaluation Worksheet 5.0 provides recommendations for the numerator and denominator for NQF performance measure #0431 Influenza Vaccination Coverage Among Healthcare Personnel (see http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68275). While The Joint Commission recommends that organizations use the Centers for Disease Control and Prevention (CDC) and the NQF proposed performance measure to calculate influenza vaccination rates for staff and licensed independent practitioners, it does not include all contracted staff. Therefore, The Joint Commission additionally recommends that organizations also track influenza vaccination rates for all individuals providing care, treatment, and services through a contract, since contracted individuals also transmit influenza.

7. The laboratory evaluates the reasons given by staff and licensed independent practitioners for declining the influenza vaccination. This evaluation occurs at least annually.
8. The laboratory improves its vaccination rates according to its established goals at least annually. (For more information, refer to Standards PI.02.01.01 and PI.03.01.01.)

Note: Laboratories with a small number of staff and licensed independent practitioners (10 or less) providing care, treatment, or services may present the data in a manner other than a percentage (for example, raw numbers).

9. The laboratory provides influenza vaccination rate data to key stakeholders which may include leaders, licensed independent practitioners, laboratory staff, and other staff at least annually.

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**Introduction to Standard IC.03.01.01 – Evaluation and Improvement**

Infection prevention and control is a continuous cycle of activities that consists of risk assessment, planning, implementation (including surveillance), evaluation, improvement, and reassessment. Evaluation and improvement of the laboratory’s infection prevention and control activities are essential steps in its efforts to prevent and control infections.

**Standard IC.03.01.01**

The laboratory evaluates the effectiveness of its infection prevention and control activities.

**Elements of Performance for IC.03.01.01**

1. The laboratory evaluates its infection prevention and control activities annually and whenever risks significantly change. The evaluation includes a review of the following:
   - The infection prevention and control prioritized risks associated with laboratory services
   - The infection prevention and control goals associated with laboratory services *(See also NPSG.07.01.01, EP 2)*
   - Implementation of the infection prevention and control activities for laboratory services

Note: Consideration should be given to emerging and re-emerging infections in the community that could potentially affect laboratory services.
6. Findings from the evaluation are communicated at least annually to the individuals or interdisciplinary group that manages the patient safety program.

7. The laboratory uses the findings of its evaluation of its infection prevention and control activities when revising its planned approach for preventing and controlling infections associated with laboratory services.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

How are responsibilities about preventing and controlling infection communicated to staff and patients? (IC.01.05.01)

**TIP:** Document and prioritize all possible risks for acquiring and transmitting infection. Create a plan for infection prevention and control using national guidelines such as recommendations from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA).

Does the laboratory have a clear process for the cleaning and disinfecting of laboratory equipment, devices, and supplies based on the level of disinfection needed? (IC.02.02.01)

**TIP:** Review staff’s competence with the laboratory’s infection control and prevention procedures including the use of personal protective equipment.

What is the process for responding to an increased number of potentially infectious patients or personnel? Is the process current? (IC.01.06.01)
Does the laboratory’s influenza vaccination program include the following? (IC.02.04.01)

- Measurable goals
- Opportunities for patients and staff to receive vaccination
- A process to identify the reasons why staff have declined the vaccination and addressing these reasons in the plan for the next season

Does the laboratory have records of annual evaluation of infection control and prevention activities? (IC.03.01.01)
# Written Documentation Checklist

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. **(Note: Documentation can be on paper or in an electronic format.)**

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IC.01.03.01, EP 3</td>
<td>The laboratory prioritizes its identified risks for acquiring and transmitting infections. These prioritized risks are documented.</td>
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<td></td>
<td>IC.01.04.01, EP 1</td>
<td>The laboratory’s written infection prevention and control goals address the following:</td>
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<td></td>
<td>IC.01.05.01, EP 2</td>
<td>The laboratory plans infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection associated with laboratory services. The description of these planned activities is documented. <strong>Note:</strong> These infection prevention and control activities may be planned by the laboratory and/or by an affiliated organization that includes the laboratory.</td>
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<td></td>
<td>IC.01.06.01, EP 4</td>
<td>The laboratory plans how it will respond to an increased number of potentially infectious patients or patient specimens.* This plan is documented.  <strong>(See also EM.01.01.01, EP 2)</strong> <em>(A response plan may include accessing the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) at <a href="http://emergency.cdc.gov/lrn/index.asp">http://emergency.cdc.gov/lrn/index.asp</a> for information and guidance.)</em></td>
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<tr>
<td></td>
<td>IC.02.04.01, EP 4</td>
<td>The laboratory includes in its infection control plan the goal of improving influenza vaccination rates.  <strong>(For more information, refer to Standard IC.01.04.01.)</strong></td>
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<tr>
<td>IC.02.04.01, EP 5</td>
<td>The laboratory sets incremental influenza vaccination goals, consistent with achieving the 90% rate established in the national influenza initiatives for 2020. <strong>Note:</strong> The US Department of Health and Human Services’ Action Plan to Prevent Healthcare-Associated Infections is located at <a href="http://www.hhs.gov/ash/initiatives/hai/hcpflu.html">http://www.hhs.gov/ash/initiatives/hai/hcpflu.html</a>.</td>
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<tr>
<td>IC.02.04.01, EP 6</td>
<td>The laboratory has a written description of the methodology used to determine influenza vaccination rates. <strong>Note:</strong> The National Quality Forum (NQF) Measure Submission and Evaluation Worksheet 5.0 provides recommendations for the numerator and denominator for NQF performance measure #0431 Influenza Vaccination Coverage Among Healthcare Personnel (see <a href="http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&amp;ItemID=68275">http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&amp;ItemID=68275</a>). While The Joint Commission recommends that organizations use the Centers for Disease Control and Prevention (CDC) and the NQF proposed performance measure to calculate influenza vaccination rates for staff and licensed independent practitioners, it does not include all contracted staff. Therefore, The Joint Commission additionally recommends that organizations also track influenza vaccination rates for all individuals providing care, treatment, and services through a contract, since contracted individuals also transmit influenza.</td>
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<tr>
<td>IC.02.04.01, EP 8</td>
<td>The laboratory improves its vaccination rates according to its established goals at least annually. (For more information, refer to Standards PI.02.01.01 and PI.03.01.01.) <strong>Note:</strong> Laboratories with a small number of staff and licensed independent practitioners (10 or less) providing care, treatment, or services may present the data in a manner other than a percentage (for example, raw numbers).</td>
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# Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Information Management (IM)

Overview
Laboratory services generate health information that must be managed systematically by the laboratory. All data and information used by the laboratory are categorized, filed, and maintained. The system should accurately capture health information generated by the laboratory services. Health information should be accessed by authorized users who will use health information to provide safe, quality services. Unauthorized access can be limited by the adoption of policies that address the privacy, security, and integrity of health information.

Depending on the type of laboratory, the system used for information management may be basic or sophisticated. As technology develops, many laboratories find their information management systems in a state of transition from paper to fully electronic or a combination of the two. Regardless of the type of system used, these standards are designed to be equally compatible with noncomputerized systems and evolving technologies.

About This Chapter
As with other chapters, planning is the initial focus of “Information Management” (IM). A well planned system meets the internal and external information needs of the laboratory with efficiency and accuracy. Planning also provides for continuity in the event that the laboratory’s operations are disrupted or fail. The laboratory also plans to protect the privacy, security, and integrity of the data and information it collects, which results in preserving confidentiality. The chapter concludes with a standard on maintaining accurate health information.

Requirements in this chapter apply to all types of information managed by the laboratory, unless the requirement specifically limits the type of information to health information. Refer to the Glossary for a definition of health information.
Chapter Outline

I. Planning for Management of Information (IM.01.01.01, IM.01.01.03)

II. Health Information
   A. Protecting the Privacy of Health Information (IM.02.01.01, IM.02.01.03)
   B. Capturing, Storing, and Retrieving Data (IM.02.02.01, IM.02.02.03, IM.02.02.05)

III. Knowledge-Based Information (IM.03.01.01)

IV. Monitoring Data and Health Information Management Processes (IM.04.01.01)

V. Laboratory Informatics Systems Records (IM.05.01.01)
Standards, Rationales, and Elements of Performance

Introduction to Standard IM.01.01.01
Planning is the most critical part of the laboratory’s information management process and requires the collaborative involvement of all levels and areas of the laboratory. The laboratory’s plan for information management considers the full spectrum of data generated and used by the laboratory; financial data, quality control data, supply inventories, and health information are examples of the different types of data that are considered in the information management planning process. Planning for the management of information does not necessarily result in a single, comprehensive written information management plan; however, planning does establish clear relationships between the laboratory’s needs and its goals. In addition to the laboratory’s goals, the laboratory’s mission, services, staff, patient safety practices, modes of service delivery, resources, and technology are considered during the information management planning process.

The flow of information within the laboratory, as well as information coming into and leaving the laboratory, is another important consideration for information management planning. Planning takes into account the data and information required to support relationships with outside providers, services, contractors, purchasers, and payers. By identifying internal and external information needs, laboratories can make information available when and where it is needed. Laboratories that understand the flow of information can achieve efficient data collection and distribution, along with effective security of health information.

Standard IM.01.01.01
The laboratory plans for managing information.

Element of Performance for IM.01.01.01
2. The laboratory identifies how data and information enter, flow within, and leave the laboratory.
Introduction to Standard IM.01.01.03
The primary goal of the information continuity process is to return the laboratory to normal operations as soon as possible with minimal downtime and no data loss. The laboratory needs to be prepared for events that could impact the availability of data and information regardless of whether interruptions are scheduled or unscheduled (due to a local or regional disaster or an emergency). Interruptions to a laboratory’s information system can potentially have a devastating impact on its ability to deliver quality laboratory services and continue its business operations. Planning for emergency situations helps the laboratory mitigate the impact that interruptions, emergencies, and disasters have on its ability to manage information. The laboratory plans for interruptions by training staff on alternative procedures, testing the laboratory’s Emergency Operations Plan, conducting regularly scheduled data backups, and testing data restoration procedures.

Regardless of whether a laboratory uses a paper-based system or an electronic system, a plan to address the process for information continuity, including knowledge-based information, should be in place. Laboratories that plan for maintaining access to electronic information systems by using various electronic backup and restoration procedures can quickly recover from interruptions with minimal downtime and data loss.

Standard IM.01.01.03
The laboratory plans for continuity of its information management processes.

Elements of Performance for IM.01.01.03
1. The laboratory has a written plan for managing interruptions to its information processes (paper-based, electronic, or a mix of paper-based and electronic) in order to provide laboratory results needed for patient care. (See also EM.01.01.01, EP 6)

The laboratory’s plan for managing interruptions to information processes addresses the following:

2. Scheduled and unscheduled interruptions of electronic information systems. (See also IM.03.01.01, EP 1; EM.01.01.01, EP 6)

3. Training for staff and licensed independent practitioners on alternative procedures to follow when electronic information systems are unavailable. (See also EM.01.01.01, EP 6)
4. Backup of electronic information systems. *(See also EM.01.01.01, EP 6)*

**Introduction to Standard IM.02.01.01**

The privacy of health information is a critical information management concern. Privacy of health information applies to electronic, paper, and verbal communications. Protecting the privacy of health information is the responsibility of all who work in the laboratory. Laboratories protect privacy by limiting the use of information to only what is needed to provide laboratory services.

Privacy, along with security, results in the confidentiality of health information. Health information is kept confidential when the information is secure (kept from intentional harm) and its use is limited (privacy). The end result of protecting the security and privacy of the information system is the preservation of confidentiality. To illustrate this relationship, confidentiality is violated in situations when an individual’s health information is used or accessed by someone who does not have permission to access the information or uses it for purposes outside of delivering laboratory services. A confidentiality violation occurs when someone is able to bypass security measures and systems to gain access to health information.* Although maintaining the confidentiality of health information and providing access to appropriate care providers can be challenging, the laboratory’s written policy on the privacy of health information can assist the laboratory in meeting both goals simultaneously.

**Standard IM.02.01.01**

The laboratory protects the privacy of health information.

**Elements of Performance for IM.02.01.01**

1. ☐ The laboratory has a written policy addressing the privacy of health information. ❋

2. The laboratory implements its policy on the privacy of health information. ❋

* For additional guidance about limiting the use of information, refer to 45 CFR 164.502(b) and 164.514(d) under “Minimum Necessary” within the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
3. The laboratory uses health information only for purposes permitted by law and regulation or as further limited by its policy on privacy.

4. The laboratory discloses health information only as authorized by the patient or as otherwise consistent with law and regulation.

**Introduction to Standard IM.02.01.03**

The integrity and security of health information are closely related. Health information is collected and processed through various information sources and systems throughout the laboratory. As a result, breaches in security can lead to the unauthorized disclosure or alteration of health information. When this occurs, the integrity of the data and information is compromised. Even simple mistakes, such as writing the incorrect date of laboratory testing, can undermine data integrity just as easily as intentional breaches. For these reasons, an examination of the use of paper and electronic information systems is considered in the laboratory’s approach to maintaining the security and integrity of health information. Regardless of the type of system, security measures should address the use of security levels, passwords, and other forms of controlled access. Because information technology and its associated security measures are continuously changing, the laboratory should do its best to stay informed about technological developments and best practices that can help it improve information security and therefore protect data integrity.

Monitoring access to health information can help laboratories be vigilant about protecting health information security. Regular security audits can identify system vulnerabilities in addition to security policy violations. For example, as part of the process, the laboratory could identify system users who have altered, edited, or deleted information. The results from this audit process can be used to validate that user permissions are appropriately set. Conducting security audits can be particularly effective in identifying when employee turnover causes vulnerabilities in security because user access and permissions were not removed or updated.

**Standard IM.02.01.03**

The laboratory maintains the security and integrity of health information.
Elements of Performance for IM.02.01.03

1. The laboratory has a written policy that addresses the security of health information, including access, use, and disclosure.

2. The laboratory has a written policy addressing the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

   Note: Only the staff authorized by the organization to perform laboratory tests are allowed to modify laboratory test results in a patient’s clinical record.

3. The laboratory has a written policy addressing the intentional destruction of health information.

4. The laboratory has a written policy that defines when and by whom the removal of health information is permitted.

   Note: Removal refers to those actions that place health information outside the laboratory’s control.

5. The laboratory protects against unauthorized access, use, and disclosure of health information.

   Note 1: This protection includes confidentiality of patient information throughout all phases of the testing process that is under the laboratory’s control.

   Note 2: Test results are released only to authorized persons, the person(s) responsible for using the test results, and/or the laboratory that initially requested the test.

6. The laboratory protects health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

7. The laboratory controls the intentional destruction of health information.

Standard IM.02.02.01

The laboratory effectively manages the collection of health information.
Rationale for IM.02.02.01
Within the laboratory, health information can come from multiple sources. The use of standardized formats and terminology can help clarify information that is used by different individuals for various purposes. Capturing data in standardized language can lead to greater data integrity and reliability, as well as an increased potential for ease of use by internal and external systems and users. The more consistent the laboratory’s efforts are to capture accurate data in standardized language, the more likely the laboratory will be to rely on that data for patient-related purposes, including reimbursement, risk management, performance improvement, and infection surveillance.

Elements of Performance for IM.02.02.01
2. ☐ The laboratory uses standardized terminology, definitions, abbreviations, acronyms, symbols, and dose designations. ☒

3. The laboratory follows its list of prohibited abbreviations, acronyms, symbols, and dose designations, which includes the following: ☒

- U,u
- IU
- Q.D., QD, q.d., qd
- Q.O.D., QOD, q.o.d, qod
- Trailing zero (X.0 mg)
- Lack of leading zero (.X mg)
- MS
- MSO₄
- MgSO₄

Note 1: A trailing zero may be used only when required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report the size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

Note 2: The prohibited list applies to all orders, preprinted forms, and medication-related documentation. Medication-related documentation can be either handwritten or electronic.
Introduction to Standard IM.02.02.03
Standardizing the collection of data, a concept that is supported by the requirements of Standard IM.02.02.03, helps with the effective dissemination of data and information. Consistency in data collection systems (paper-based, electronic, or a combination) creates the foundation for retrieving and disseminating data and information in the most useful format. For information about data collection and dissemination, visit the websites of the Office of the National Coordinator for Health Information Technology (ONC) (http://www.healthit.gov/) and the Certification Commission for Healthcare Information Technology (CCHIT) (http://www.cchit.org).

Standard IM.02.02.03
The laboratory retrieves, disseminates, and transmits health information in useful formats.

Rationale for IM.02.02.03
The ease of use of health information between systems and users contributes to its potential usefulness within the laboratory and for external reporting purposes. Data stored in different formats cannot easily be converted to a new format or transferred to other organizations or providers. As more laboratories automate various processes and activities, these systems need to allow for transmitting and receiving critical data while maintaining data integrity.

Elements of Performance for IM.02.02.03
1. The laboratory has written policies addressing data capture, display, transmission, and retention. ➔
2. The laboratory’s storage and retrieval systems make health information accessible when needed for laboratory services. (See also IC.01.02.01, EP 1) ➔
3. The laboratory disseminates data and information in useful formats within time frames that are defined by the laboratory and consistent with law and regulation. ➔

Standard IM.02.02.05
The laboratory informatics system (LIS) provides reliable patient information.
Elements of Performance for IM.02.02.05

1. The laboratory has written policies and procedures that define validation criteria for assessing functionality in all environments of the laboratory informatics system that include the following:  
   - Data capture  
   - Data display  
   - Data transmission  
   - Data retention†

2. The laboratory validates the laboratory information system performance upon installation. The validation activities are documented.

3. The laboratory has written policies and procedures to verify LIS and middleware functions after the following:  
   - Modification of hardware  
   - Installation of new software  
   - Following restoration of data files

   The verification activities are documented.

Standard IM.03.01.01
Knowledge-based information resources are available, current, and authoritative.

Elements of Performance for IM.03.01.01

1. The laboratory provides access to knowledge-based information resources during hours of operation. (See also IM.01.01.03, EP 2)

3. The laboratory has an ongoing process to assess the knowledge-based information needs of the laboratory and its staff.

4. The laboratory uses the assessment of knowledge-based information as a basis for planning access to knowledge-based information resources.

Standard IM.04.01.01
The laboratory maintains accurate health information.

† Additional information can be found in the current editions of Clinical and Laboratory Standards Institute (CLSI) documents AUTO08 (Managing and Validating Laboratory Information Systems) and AUTO12 (Specimen Labels: Content and Location, Fonts, and Label Orientation).
Rationale for IM.04.01.01
The integrity and quality of health information influences the usefulness and effectiveness of all internal and downstream systems, as well as external reporting. When the integrity of the data has been compromised, additional resources will be needed to scan the data and correct errors. Inaccurate data can lead to poor decision making.

Element of Performance for IM.04.01.01
1. The laboratory has processes to check the accuracy of laboratory-related health information. R

   Note: The laboratory has the flexibility to determine what health information needs to be checked for accuracy and the frequency with which it will be checked.

Standard IM.05.01.01
A written record of laboratory informatics system history is maintained.

Elements of Performance for IM.05.01.01
1. Written records detailing dates of initial installation and subsequent modifications to laboratory informatics systems are available for review. R

2. Written records of repair and maintenance of the laboratory informatics system are available for review. R
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

When was the plan for managing interruptions to electronic information systems last tested? (IM.01.01.03)

TIP: For efficiency, consider testing the plan for managing interruptions to electronic information systems when testing the Emergency Operations Plan.

Has the security of protected information been maintained? (IM.02.01.01, IM.02.01.03)

TIP: Review various scenarios when staff access protected information. Can others access any information they should not have access to?

Does the laboratory use standardized formats and terminology even if is used by different individuals for various purposes? (IM.02.02.01)

How does the laboratory verify its laboratory informatics system (LIS) and middleware functions so they consistently provide reliable patient information? (IM.02.02.05)
What additional resources and action plans are available when errors and inaccurate data are discovered? (IM.04.01.01)
Written Documentation Checklist
This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. (Note: Documentation can be on paper or in an electronic format.)

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
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<tbody>
<tr>
<td></td>
<td>IM.01.01.03, EP 1</td>
<td>The laboratory has a written plan for managing interruptions to its information processes (paper-based, electronic, or a mix of paper-based and electronic). (See also EM.01.01.01, EP 6)</td>
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<td>IM.02.01.01, EP 1</td>
<td>The laboratory has a written policy addressing the privacy of health information.</td>
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<tr>
<td></td>
<td>IM.02.01.03, EP 1</td>
<td>The laboratory has a written policy that addresses the security of health information, including access, use, and disclosure.</td>
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<tr>
<td></td>
<td>IM.02.01.03, EP 2</td>
<td>The laboratory has a written policy addressing the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction. Note: Only the staff authorized by the organization to perform laboratory tests are allowed to modify laboratory test results in a patient's clinical record.</td>
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<tr>
<td></td>
<td>IM.02.01.03, EP 3</td>
<td>The laboratory has a written policy addressing the intentional destruction of health information.</td>
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<td>IM.02.01.03, EP 4</td>
<td>The laboratory has a written policy that defines when and by whom the removal of health information is permitted. Note: Removal refers to those actions that place health information outside the laboratory's control.</td>
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<tr>
<td></td>
<td>IM.02.02.01, EP 2</td>
<td>The laboratory uses standardized terminology, definitions, abbreviations, acronyms, symbols, and dose designations.</td>
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<tr>
<td></td>
<td>IM.02.02.03, EP 1</td>
<td>The laboratory has written policies addressing data capture, display, transmission, and retention.</td>
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</tbody>
</table>
| IM.02.02.05, EP 1 | The laboratory has written policies and procedures that define validation criteria for assessing functionality in all environments of the laboratory informatics system that include the following:  
- Data capture  
- Data display  
- Data transmission  
- Data retention*  
* Additional information can be found in the current editions of Clinical and Laboratory Standards Institute (CLSI) documents AUTO08 (Managing and Validating Laboratory Information Systems) and AUTO12 (Specimen Labels: Content and Location, Fonts, and Label Orientation). |
| IM.02.02.05, EP 2 | The laboratory validates the laboratory information system performance upon installation. The validation activities are documented. |
| IM.02.02.05, EP 3 | The laboratory has written policies and procedures to verify LIS and middleware functions after the following:  
- Modification of hardware  
- Installation of new software  
- Following restoration of data files  
The verification activities are documented. |
| IM.05.01.01, EP 1 | Written records detailing dates of initial installation and subsequent modifications to laboratory informatics systems are available for review. |
| IM.05.01.01, EP 2 | Written records of repair and maintenance of the laboratory informatics system are available for review. |
## Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Leadership (LD)

Overview
The safety and quality of laboratory services depend on many factors, including the following:
- A culture that fosters safety as a priority for everyone who works in the laboratory
- The planning and provision of services that meet the needs of patients
- The availability of resources—human, financial, and physical—for providing laboratory services
- The existence of competent staff and other care providers
- Ongoing evaluation of and improvement in performance

Management of these important functions is the direct responsibility of leaders; they are, in effect, responsible for the services that the laboratory provides to its patients. In laboratories with a governing body, governance has ultimate responsibility for this oversight. In larger laboratories, different individuals or groups may be assigned different responsibilities, and they bring with them different skills, experience, and perspectives. In these situations, the way that the leaders interact with each other and manage their assigned accountabilities can affect overall laboratory performance. In smaller laboratories, these responsibilities may be handled by just one or two individuals. This chapter addresses the role of leaders in managing their diverse and, at times, complex responsibilities.

Leaders shape the laboratory’s culture, and the culture, in turn, affects how the laboratory accomplishes its work. A healthy, thriving culture is built around the laboratory’s mission and vision, which reflect the core values and principles that the laboratory finds important. Leaders must ask some basic questions in order to provide this focus: How does the laboratory plan to meet the needs of its population? By what ethical standards will the laboratory operate? What does the laboratory want to accomplish through its work? Once leaders answer these questions, the culture of the laboratory will begin to take shape. Leaders also have an obligation to set an example of how to work together to fulfill the laboratory’s mission.

On a more practical level, leaders oversee operations and guide the laboratory on a day-to-day basis. They keep operations running smoothly so that the important work of the laboratory—serving its patients—can continue.
To meet their obligations effectively, leaders must collaborate, which means working together in a spirit of collegiality to achieve a common end. In smaller laboratories, this may mean that a single leader or small group of leaders works closely with staff in order to meet the laboratory’s managerial needs. In this case, key staff members share governance and decision making with senior leadership in order to direct the day-to-day operations, assess needs, secure resources, and plan for the future. Senior managers direct the day-to-day operations of the laboratory; governance determines what resources the laboratory needs and then secures those resources.

**Proactive Risk Assessment**

By undertaking a proactive risk assessment, a laboratory can correct process problems and reduce the likelihood of experiencing adverse events. A laboratory can use a proactive risk assessment to evaluate a process to see how it could fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. The term “process” applies broadly to processes that are integral to laboratory services, such as collecting specimens.

Proactive risk assessments are useful for analyzing new processes before they are implemented. Processes need to be designed with a focus on quality and reliability to achieve desired outcomes and protect patients. Proactive risk assessments are also used to evaluate existing processes that have the greatest potential for affecting patient safety. A laboratory’s choice of which process it will assess may be based in part on information published periodically by The Joint Commission about frequently occurring sentinel events and processes that pose high risk to patients.

A proactive risk assessment increases understanding within the laboratory about the complexities of process design and management and what could happen if the process fails. If an adverse event occurs, the organization may be able to use the information gained from the prior risk assessment to minimize the consequences of the event—and to avoid simply reacting to it.

Although there are several methods that could be used to conduct a proactive risk assessment, the following steps make up one approach:

1. Describe the chosen process (for example, through the use of a flowchart).
2. Identify ways in which the process could break down or fail to perform its desired functions, which is often referred to as failure mode.
3. Identify the possible effects that a breakdown or failure of the process could have on patients and the seriousness of the possible effects.
4. Prioritize the potential process breakdowns or failures.
5. Determine why the prioritized breakdowns or failures could occur, which may involve performing a hypothetical root cause analysis.
6. Design or redesign the process and/or underlying systems to minimize the risk of the effects on patients.
7. Test and implement the newly designed or redesigned process.
8. Monitor the effectiveness of the newly designed or redesigned process.

**About This Chapter**

This chapter is divided into four sections: “Leadership Structure,” “Leadership Relationships,” “Organization Culture and System Performance Expectations,” and “Operations.” The laboratory’s culture, systems, and leadership structure and relationships all come together to shape and drive its operations.

The standards in the “Leadership Structure” section identify and define the various leadership groups and their responsibilities. The standards in “Leadership Relationships” address the development of the laboratory’s mission, vision, and goals, as well as communication among leaders. The standards in the “Organization Culture and System Performance Expectations” section focus on the framework for the laboratory’s culture and systems. These standards also demonstrate how leaders help shape the culture of a laboratory and how culture, in turn, affects important systems within the laboratory (for example, data use, planning, communication, changing performance, staffing).

The standards in the “Operations” section address the functions that are important to patient safety and high-quality laboratory services. Some leaders may not be directly involved in the day-to-day operations of the laboratory, but the decisions they make and the initiatives they implement do affect operations.
Chapter Outline

I. Leadership Structure
   A. Leadership Structure (LD.01.01.01)
   B. Governance Accountabilities (LD.01.03.01)

II. Leadership Relationships
   A. Mission, Vision, and Goals (LD.02.01.01)

III. Organization Culture and System Performance Expectations
   A. Culture of Safety and Quality (LD.03.01.01)
   B. Using Data and Information (LD.03.02.01)
   C. Organizationwide Planning (LD.03.03.01)
   D. Communication (LD.03.04.01)
   E. Change Management and Performance Improvement (LD.03.05.01)
   F. Staffing (LD.03.06.01)

IV. Operations
   A. Administration (LD.04.01.01, LD.04.01.03, LD.04.01.11)
   B. Ethical Issues (LD.04.02.01 and LD.04.02.03)
   C. Meeting Patient Needs (LD.04.03.01, LD.04.03.09)
   D. Managing Safety and Quality (LD.04.04.01, LD.04.04.03, LD.04.04.05)
   E. Laboratory Administration (LD.04.05.01, LD.04.05.03, LD.04.05.05, LD.04.05.07, LD.04.05.09, LD.04.05.11, LD.04.05.13, LD.04.05.15)
Introduction to Leadership Structure, Standards LD.01.01.01 Through LD.01.03.01

Each laboratory, regardless of its complexity, has a structured leadership. Many leadership responsibilities directly affect the provision of laboratory services, as well as the day-to-day operations of the laboratory. In some cases, these responsibilities will be shared among leaders, and in other cases, a particular leader has primary responsibility. Individual leaders may have several different roles. Regardless of the laboratory’s structure, it is important that leaders carry out all their responsibilities.

A variety of individuals may work in the laboratory, including licensed independent practitioners, staff, volunteers, students, and independent contractors. These standards describe the overall responsibility of governance for the safety and quality of services provided by all of these individuals.

How well leaders work together is key to effective laboratory performance, and the standards emphasize this. Leaders with different responsibilities—governance, management, and the clinical staff—bring different skills, experiences, and perspectives to the laboratory. Working together means that leaders have the opportunity to participate in discussions and have their opinions heard. Depending on the topic and the laboratory, individuals may participate in decision making, and the governing body may delegate decision making to certain leaders. Final decisions, however, are always the ultimate responsibility of governance; this key principle is assumed in any standard that describes how leaders work together.

Standard LD.01.01.01
The laboratory has a leadership structure.

Note: If the laboratory is part of a Joint Commission–accredited organization, this standard is not applicable. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting this standard.
Rationale for LD.01.01.01
Every laboratory has a leadership structure to support operations. Many functions need to be carried out, including governance, administration, and oversight of laboratory services. In some laboratories leaders have distinct roles in carrying out these functions; in others a single individual may perform all leadership functions.

Elements of Performance for LD.01.01.01
1. **For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories):** The laboratory identifies those responsible for governance.

2. **For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories):** Governance identifies those responsible for planning, management, and operational activities.

3. **For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories):** Governance identifies those responsible for the provision of laboratory services.

6. The laboratory has a written organizational plan or chart that delineates staff reporting relationships.

Standard LD.01.03.01
Governance is ultimately accountable for the safety and quality of laboratory services.

**Note:** If the laboratory is part of a Joint Commission–accredited organization, this standard is not applicable. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting this standard.

Rationale for LD.01.03.01
Governance’s ultimate responsibility for safety and quality derives from its legal responsibility and operational authority for laboratory performance. In this context, governance provides for internal structures and resources, including staff, that support safety and quality.
Elements of Performance for LD.01.03.01

1. Governance defines in writing its responsibilities.

2. Governance provides for organization management and planning.

3. Governance approves the laboratory’s written scope of services.

4. Governance selects the laboratory director.

5. Governance provides for the resources needed to maintain safe, quality laboratory services.

6. Governance works with laboratory leaders to annually evaluate the laboratory’s performance in relation to its mission, vision, and goals.

Introduction to Leadership Relationships, Standard LD.02.01.01

How well leaders work together and manage conflict affects a laboratory’s performance. In fulfilling its role, the governance involves senior managers and leaders of clinical staff in governance and management functions.

Good relationships thrive when leaders work together to develop the mission, vision, and goals of the laboratory; encourage honest and open communication; and address conflicts of interest.
Standard LD.02.01.01
The mission, vision, and goals of the laboratory support the safety and quality of laboratory services.

Rationale for LD.02.01.01
The primary responsibility of leaders is to provide for the safety and quality of laboratory services. The purpose of the laboratory’s mission, vision, and goals is to define how the laboratory will achieve safety and quality. The leaders are more likely to be aligned with the mission, vision, and goals when they create them together. The common purpose of the laboratory is most likely achieved when it is understood by all who work in or are served by the laboratory.

Elements of Performance for LD.02.01.01
1. Leaders work together to create the laboratory’s mission, vision, and goals.
2. The laboratory’s mission, vision, and goals guide the actions of leaders.
3. Leaders communicate the mission, vision, and goals to staff and the population(s) the laboratory serves.

Introduction to Organization Culture and System Performance Expectations, Standards LD.03.01.01 Through LD.03.06.01
An organization’s culture reflects the beliefs, attitudes, and priorities of its members, and it influences the effectiveness of performance. Although there may be a dominant culture, in many larger laboratories diverse cultures exist that may or may not share the same values. In fact, diverse cultures can exist even in smaller laboratories. Laboratory performance can be effective in either case. Successful laboratories will work to develop a culture of safety and quality.

In a culture of safety and quality, all individuals are focused on maintaining excellence in performance. They accept the safety and quality of patient laboratory services as personal responsibilities and work together to minimize any harm that might result from unsafe or poor quality of laboratory services. Leaders create this culture by demonstrating their commitment to safety and quality and by taking actions to achieve the desired state. In a culture of this kind, one finds teamwork, open discussions of concerns about safety and
quality, and the encouragement of and reward for internal and external reporting of safety and quality issues. The focus of attention is on the performance of systems and processes instead of the individual, although reckless behavior and a blatant disregard for safety are not tolerated. Laboratories are committed to ongoing learning and have the flexibility to accommodate changes in technology, science, and the environment.

The leaders provide for the effective functioning of the organization with a focus on safety and quality. Leaders plan, support, and implement key systems critical to this effort. The Joint Commission has identified five key systems that influence the effective performance of a laboratory:
1. Using data
2. Planning
3. Communicating
4. Changing performance
5. Staffing

The following diagram illustrates the role of leadership in the performance of these systems.
Leadership provides the foundation for effective performance. The five key systems serve as pillars that are based on the foundation set by leadership and, in turn, support the many laboratorywide processes that are important to individual laboratory services. Culture permeates the entire structure.

The five key systems are interrelated and need to function well together. The integration of these systems throughout the laboratory will facilitate the effective performance of the laboratory as a whole. Leaders develop a vision and goals for the performance of these systems and evaluate their performance. Leaders use results to develop strategies for future improvements.

Performance of many aspects of these systems may be directly observable. But in many cases laboratories demonstrate compliance through performance in standards located in other sections of this manual. These Leadership standards are cited when patterns of performance suggest laboratorywide issues.

The effective performance of these systems results in a culture in which safety and quality are priorities. The laboratory demonstrates this through a proactive, nonpunitive culture that is monitored and sustained by related reporting systems and improvement initiatives.

Many of the concepts in the following section have long existed in the standards.

**Standard LD.03.01.01**
Leaders create and maintain a culture of safety and quality throughout the laboratory.

**Rationale for LD.03.01.01**
Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the laboratory. Leaders demonstrate their commitment to quality and set expectations for those who work in the laboratory. Leaders evaluate the culture on a regular basis using a variety of methods, such as formal surveys, focus groups, staff interviews, and data analysis.

Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Behavior that intimidates others and affects morale or staff turnover undermines a culture of safety and can be harmful to patient care. Leaders must address such behavior in individuals working at all levels of the laboratory, including management, clinical and administrative staff, licensed independent practitioners, and governing body members.
Elements of Performance for LD.03.01.01

1. Leaders regularly evaluate the culture of safety and quality.
2. Leaders prioritize and implement changes identified by the evaluation.
3. Leaders development a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
4. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

Standard LD.03.02.01

The laboratory uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

Rationale for LD.03.02.01

Data help laboratories make the right decisions. When decisions are supported by data, laboratories are more likely to move in directions that help them achieve their goals. Successful laboratories measure and analyze their performance. When data are analyzed and turned into information, this process helps laboratories see patterns and trends and understand the reasons for their performance. Many types of data are used to evaluate performance, including data on outcomes of care, performance on safety and quality initiatives, patient satisfaction, process variation, and staff perceptions.

Elements of Performance for LD.03.02.01

1. Leaders set expectations for using data and information to improve the safety and quality of laboratory services.
2. Leaders are able to describe how data and information are used to create a culture of safety and quality.
3. The laboratory uses processes to support systematic data and information use.
4. Leaders provide the resources needed for data and information use, including staff, equipment, and information systems.
5. The laboratory uses data and information in decision making that supports the safety and quality of laboratory services. (See also PI.02.01.01, EP 8)
6. The laboratory uses data and information to identify and respond to internal and external changes in the environment.
7. Leaders evaluate how effectively data and information are used throughout the laboratory.

**Standard LD.03.03.01**

Leaders use laboratorywide planning to establish structures and processes that focus on safety and quality.

**Rationale for LD.03.03.01**

Planning is essential to the following:

- The achievement of short- and long-term goals
- Meeting the challenge of external changes
- The design of services and work processes
- The creation of communication channels
- The improvement of performance
- The introduction of innovation

Planning includes contributions from the populations served, from those who work for the laboratory, and from other interested groups or individuals.

**Elements of Performance for LD.03.03.01**

1. Planning activities focus on improving patient safety and health care quality.
2. Leaders can describe how planning supports a culture of safety and quality.
3. Planning is systematic, and it involves designated individuals and information sources.
4. Leaders provide the resources needed to support the safety and quality of laboratory services.
5. Safety and quality planning is laboratorywide.
6. Planning activities adapt to changes in the environment.
7. Leaders evaluate the effectiveness of planning activities.

**Standard LD.03.04.01**

The laboratory communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.
Rationale for LD.03.04.01
Effective communication is essential among individuals and groups within the laboratory, and between the laboratory and external parties. Poor communication often contributes to adverse events and can compromise safety and quality of laboratory services. Effective communication is timely, accurate, and usable by the audience.

Elements of Performance for LD.03.04.01
1. Communication processes foster the safety of the patient and the quality of care.
2. Leaders are able to describe how communication supports a culture of safety and quality.
3. Communication is designed to meet the needs of internal and external users.
4. Leaders provide the resources required for communication, based on the needs of patients, staff, and management.
5. Communication supports safety and quality throughout the laboratory. (See also LD.04.04.05, EP 6)
6. When changes in the environment occur, the laboratory communicates those changes effectively.
7. Leaders evaluate the effectiveness of communication methods.

Standard LD.03.05.01
Leaders implement changes in existing processes to improve the performance of the laboratory.

Rationale for LD.03.05.01
Change is inevitable, and agile laboratories are able to manage change and rapidly execute new plans. The ability of leaders to manage change is necessary for performance improvement, for successful innovation, and to meet environmental challenges. The laboratory integrates change into all relevant processes so that its effectiveness can be sustained, assessed, and measured.

Elements of Performance for LD.03.05.01
1. Structures for managing change and performance improvements exist that foster the safety of the patient and the quality of laboratory services.
2. Leaders are able to describe how the laboratory’s approach to performance improvement and its capacity for change support a culture of safety and quality.
3. The laboratory has a systematic approach to change and performance improvement.

4. Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training.

5. The management of change and performance improvement supports both safety and quality throughout the laboratory.

6. The laboratory’s internal structures can adapt to changes in the environment.

7. Leaders evaluate the effectiveness of processes for the management of change and performance improvement.

**Standard LD.03.06.01**

Those who work in the laboratory are focused on improving safety and quality.

**Rationale for LD.03.06.01**

The safety and quality of laboratory services are highly dependent on the people who work in the laboratory. The mission, scope, and complexity of services define the design of work processes and the skills and number of individuals needed. In a successful laboratory, work processes and the environment make safety and quality paramount. This standard, therefore, applies to all those who work in or for the laboratory, including staff and licensed independent practitioners.

**Elements of Performance for LD.03.06.01**

1. Leaders design work processes to focus individuals on safety and quality issues.  

2. Leaders are able to describe how those who work in the laboratory support a culture of safety and quality.

3. Leaders provide for a sufficient number and mix of individuals to support safe, quality laboratory services.  

**Note 1:** The following indicators demonstrate adequacy of technical and support staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- Overtime is not significantly high.
- There are no lapses in quality control and proficiency testing.
- Performance testing and documentation of equipment maintenance have no lapses.
- Turnaround time is not prolonged.
The quality of specimens, cultures, differential testing methods, or results is not jeopardized.

Note 2: The following indicators demonstrate adequacy of supervisory staff to meet the service needs of the patients, including evenings, weekends, and holidays:

- The background and experience of supervisory staff are consistent with work assignments and responsibilities.
- Quality control, proficiency testing, and maintenance are well performed and evaluated.
- Policies and procedures are current and well executed.
- Turnaround time is satisfactory.
- Record systems are well organized and current.
- Quality improvement mechanisms are implemented.
- Test analyses and specimen examinations are monitored to ensure that acceptable levels of analytic performance are maintained.

4. Those who work in the laboratory are competent to complete their assigned responsibilities.

5. Those who work in the laboratory adapt to changes in the environment.

6. Leaders evaluate the effectiveness of those who work in the laboratory to promote safety and quality.

Introduction to Operations, Standards
LD.04.01.01 Through LD.04.05.15

Although some leaders may not be involved in the day-to-day, hands-on operations of the laboratory, their decisions and work affect, either directly or indirectly, every aspect of operations. They are the driving force behind the culture of the laboratory. Leaders establish the ethical framework in which the laboratory operates, create policies and procedures, and secure resources and services that support patient safety and quality laboratory services. Policies, procedures, resources, and services are all influenced by the culture of the laboratory and, in turn, influence the culture.

Standard LD.04.01.01

The laboratory complies with law and regulation.
Elements of Performance for LD.04.01.01

1. The laboratory is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the services for which the laboratory is seeking accreditation from The Joint Commission.  

**Note 1:** Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, US Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.

2. The laboratory provides laboratory services in accordance with licensure requirements, laws, and rules and regulations.

3. Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.

4. Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.

**Standard LD.04.01.03**
The laboratory develops an annual operating budget and, when needed, a long-term capital expenditure plan.

**Elements of Performance for LD.04.01.03**

1. Leaders solicit comments from those who work in the laboratory when developing the operational and capital budgets.

3. The operating budget reflects the laboratory’s goals and objectives.

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*For more information on how to obtain a CLIA certificate, see http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)*
Standard LD.04.01.11
The laboratory makes space and equipment available as needed for the provision of laboratory services.

Rationale for LD.04.01.11
The resources allocated to services provided by the laboratory have a direct effect on patient outcomes. Leaders should place highest priority on high-risk or problem-prone processes that can affect patient safety.

Element of Performance for LD.04.01.11
1. The laboratory director routinely communicates with the leaders of the laboratory about space, equipment, and other resources required for services.
   
   Note: Testing activities that require special equipment, staff, and facilities are performed only when the required resources are available.

Standard LD.04.02.01
The leaders address any conflict of interest involving licensed independent practitioners and/or staff that affects or has the potential to affect the safety or quality of laboratory services.

Elements of Performance for LD.04.02.01
1. The leaders define conflict of interest involving licensed independent practitioners or staff. This definition is in writing.
2. The leaders develop a written policy that defines how the laboratory will address conflicts of interest involving licensed independent practitioners and/or staff.
3. Existing or potential conflicts of interest involving licensed independent practitioners and/or staff, as defined by the laboratory, are disclosed.
4. The laboratory reviews its relationships with other care providers, educational institutions, manufacturers, and payers to determine whether conflicts of interest exist and whether they are within law and regulation.

Standard LD.04.02.03
Ethical principles guide the laboratory’s business practices.
Elements of Performance for LD.04.02.03

1. The laboratory has a process that allows staff, patients, and families to address ethical issues or issues prone to conflict.

2. The laboratory uses its process to address ethical issues or issues prone to conflict.

11. Patients and other customers are billed for only those services provided.

Standard LD.04.03.01
The laboratory provides services that meet patient needs.

Element of Performance for LD.04.03.01

1. The needs of the population(s) served guide decisions about which services will be provided directly or through referral, consultation, contractual arrangements, or other agreements.

Introduction to Oversight of Laboratory Services Provided Through Contractual Agreement, Standard LD.04.03.09
The same level of care should be delivered to patients regardless of whether services are provided directly by the laboratory or through contractual agreement. Leaders provide oversight to make sure that laboratory services provided directly are safe and effective. Likewise, leaders must also oversee contracted services to make sure that they are provided safely and effectively. Standard LD.04.03.09 outlines the requirements for leadership oversight of laboratory services provided through contractual agreement.

The only contractual agreements subject to the requirements in Standard LD.04.03.09 are those for the provision of laboratory services provided to the laboratory’s patients. This standard does not apply to contracted services that are not directly related to patient care. In addition, contracts for consultation or referrals are not subject to the requirements in Standard LD.04.03.09. However, regardless of whether or not a contract is subject to this standard, the actual performance of any contracted service is evaluated at the other standards in this manual appropriate to the nature of the contracted service.
Monitoring Contracted Services

The expectations that leaders set for the performance of contracted services should reflect basic principles of risk reduction, safety, staff competence, and performance improvement. Although leaders have the same responsibility for oversight of contracted services outside the laboratory’s expertise as they do for contracted services within the laboratory’s expertise, it is more difficult to determine how to monitor such services. In these cases, information from relevant professional organizations can provide guidance for setting expectations.

The elements of performance do not prescribe the methods for evaluating contracted services; leaders are expected to select the best methods for their laboratory to oversee the quality and safety of services provided through contractual agreement. Examples of sources of information that may be used for evaluating contracted services include the following:

- Review of information about the contractor’s Joint Commission accreditation or certification status
- Direct observation of the provision of care
- Audit of documentation, including medical records
- Review of incident reports
- Review of periodic reports submitted by the individual or laboratory providing services under contractual agreement
- Collection of data that address the efficacy of the contracted service
- Review of performance reports based on indicators required in the contractual agreement
- Input from staff and patients
- Review of patient satisfaction studies
- Review of results of risk management activities

In the event that contracted services do not meet expectations, leaders take steps to improve laboratory services. In some cases, it may be best to work with the contractor to make improvements, whereas in other cases it may be best to renegotiate or terminate the contractual relationship. When leaders anticipate the renegotiation or termination of a contractual agreement, planning needs to occur so that the continuity of laboratory services is not disrupted.
Standard LD.04.03.09

Laboratory services provided through contractual agreement are provided safely and effectively.

Elements of Performance for LD.04.03.09

1. Clinical leaders have an opportunity to provide advice about the sources of clinical services to be provided through contractual agreement. 

2. The laboratory describes, in writing, the nature and scope of services provided through contractual agreements. 

   Note: A written agreement (such as a formal contract) is not required for reference laboratories; however, it is required for a contractual agreement in which a major portion of laboratory testing is provided by an outside laboratory.

3. Designated leaders approve contractual agreements.

4. Leaders monitor contracted services by establishing expectations for the performance of the contracted services. 

   Note: When the laboratory contracts with another accredited organization for patient laboratory services to be provided off site, it can do the following:
   - Verify that all licensed independent practitioners who will be providing laboratory services have appropriate privileges by obtaining, for example, a copy of the list of privileges.
   - Specify in the written agreement that the contracted organization will ensure that all contracted services provided by licensed independent practitioners will be within the scope of their privileges.

5. Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services. 

   Note: A written description of the expectations can be provided either as part of the written agreement or in addition to it.

6. Leaders monitor contracted services by evaluating these services in relation to the laboratory’s expectations.

7. Leaders take steps to improve contracted services that do not meet expectations. 

   Note: Examples of improvement efforts to consider include the following:
   - Increase monitoring of the contracted services.
Leaders establish priorities for performance improvement. (Refer to the “Performance Improvement” [PI] chapter.)

Elements of Performance for LD.04.04.01

1. Leaders set priorities for performance improvement activities and patient health outcomes. *(See also PI.01.01.01, EPs 1 and 3)*

2. Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. *(See also PI.01.01.01, EPs 7, 8, and 23)*

3. Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.

4. Performance improvement occurs laboratorywide.

Standard LD.04.04.03

New or modified services or processes are well designed.

Elements of Performance for LD.04.04.03

1. The laboratory’s design of new or modified services or processes incorporates the needs of patients, staff, and others. *(R)*

2. The laboratory’s design of new or modified services or processes incorporates the results of performance improvement activities.

4. The laboratory’s design of new or modified services or processes incorporates evidence-based information in the decision-making process.

**Note:** For example, evidence-based information could include practice guidelines, successful practices, information from current literature, and clinical standards.
5. The laboratory’s design of new or modified services or processes incorporates information about sentinel events. (See also LD.04.04.05, EP 6; LD.04.04.05, EP 11)

**Note:** A proactive risk assessment is one of several ways to assess potential risks to patients. For suggested components, refer to the Proactive Risk Assessment section at the beginning of this chapter.

**Introduction to Standard LD.04.04.05**

This standard addresses the need for laboratories to manage and understand the reasons for sentinel events, and to take action on them when they occur.

**Standard LD.04.04.05**

The laboratory manages safety issues.

**Elements of Performance for LD.04.04.05**

6. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.04.01, EP 5; LD.04.04.03, EP 5)

**Note:** This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.

7. The leaders define patient safety event and communicate this definition throughout the organization.

**Note:** At a minimum, the organization’s definition includes those events subject to review in the “Sentinel Events” (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a close call or near miss.

8. The laboratory conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the “Sentinel Events” (SE) chapter of this manual.
11. To improve safety, the laboratory analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. *(See also LD.04.03, EP 5)*

**Standard LD.04.05.01**

Laboratory leadership is effective.

**Rationale for LD.04.05.01**

The director of pathology and clinical laboratory services, as listed on the laboratory Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, oversees and is ultimately responsible for the laboratory’s activities, but this does not prevent him or her from assigning specific tasks to others (for example, assigning responsibility for consultation to a pathologist). Laboratory directors are responsible for operations and measuring, assessing, and continuously improving their department’s performance. Pathology and clinical laboratory services are organized, directed, and staffed in keeping with the scope of services offered.

Appropriate clinically trained individuals provide or supervise clinical consultation, which consists of the interpretation, evaluation, and application of test results in diagnosing and treating a particular patient. It does not include providing a practitioner with data or general information, such as laboratory test results, reference intervals (normal ranges) for test results, general medical information pertaining to differential diagnoses related to a test result, or general information about additional tests that can be helpful.

**Note:** *In a hospital, such clinical consultation is the responsibility of a physician (in the case of oral pathology, a physician or a dental oral pathologist). If the director of the clinical laboratory services in a hospital is a doctoral scientist, clinical consultation is provided by a qualified physician. If the director is a physician, he or she provides the consultation.*

**Elements of Performance for LD.04.05.01**

1. Oversight required for effective laboratory leadership provides the following:
   - Technical expertise
   - Supervision

**Note:** *The general supervisor is responsible for the day-to-day supervision of the laboratory operation and staff who perform patient testing. *(See also QSA.02.11.01, EP 3)*
A list of current laboratory test methods, performance specifications, and factors which may interfere with test results made available, upon request, to clients.

Clinical consultation, including matters related to the quality of the test results reported and their interpretation concerning specific patient conditions and the appropriateness of the testing ordered to meet the clinical expectations and interpretation of test results, to the laboratory’s patients.

2. The technical consultant and/or technical supervisor is responsible for the technical and scientific oversight of the laboratory.

3. The laboratory director is accessible to the laboratory to provide onsite, telephone, or electronic consultation as necessary.

4. The laboratory director establishes communication in the laboratory and throughout the organization through participation, to the extent required, in such activities as committees, in-service programs, and other functions.

5. All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

6. The laboratory director is responsible for no more than five Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificates (including non-waived and PPM certificates) or less if specified by state law.

7. The laboratory director is responsible for the proper performance of all of his or her duties, including when those duties are delegated. (See also HR.01.02.03, EPs 2 and 7)

8. The laboratory director approves current reference intervals (normal values).

9. The laboratory director makes the documentation for the basis of reference intervals (normal values) available to staff upon request.

**Standard LD.04.05.03**
The laboratory director is responsible for determining the qualifications and competence of each laboratory staff member.

**Elements of Performance for LD.04.05.03**

1. The laboratory director determines the competence and qualifications of each staff member. (See also IC.01.01.01, EP 3)
2. The laboratory director determines that the level of testing complexity is commensurate with the education, training, experience, and technical abilities of each staff member. [R]

3. The laboratory director determines which procedures and tests each staff member is qualified and authorized to perform. [R]

4. The laboratory director determines that the level of supervision provided is commensurate with the education, training, and experience of each staff member. [R]

5. The laboratory director requires that each staff member demonstrate the ability to perform all duties before actually testing patient specimens. [R]

6. The laboratory director requires that each staff member maintain the competence to perform required tasks. [R]

**Standard LD.04.05.05**
The laboratory director, technical consultant, and/or technical supervisor provide for orientation, in-service training, and continuing education.

**Elements of Performance for LD.04.05.05**

1. The laboratory director, technical consultant, and/or technical supervisor provide for orientation, in-service training, and continuing education.

2. The laboratory director defines and approves policies for the following:
   - Orientation
   - In-service training
   - Continuing education

**Standard LD.04.05.07**
The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.

**Elements of Performance for LD.04.05.07**

1. The laboratory director, technical consultant, and/or technical supervisor define the laboratory’s criteria for the following:
   - Quality control
   - Proficiency testing
   - Reporting of results
2. The laboratory director, technical consultant, and/or technical supervisor define or approve other criteria used in the preanalytical, analytical, and postanalytical phases of testing.

3. The laboratory director, technical consultant, and/or technical supervisor ascertain that test methodologies and equipment fulfill the following criteria:
   - They meet the needs of the patient population.
   - They are verified to determine accuracy, precision, and other pertinent performance characteristics.
   - They are adequate in scope.
   - They are capable of providing the quality of results required by the clinical staff.

4. The laboratory director, technical consultant, and/or technical supervisor ascertain that the laboratory is enrolled and successfully participates in an approved proficiency testing program that is relevant for each test performed. *(See also QSA.01.01.01, EP 1)*

5. The laboratory director, technical consultant, and/or technical supervisor review quality control and proficiency testing data.

6. The laboratory director, technical consultant, and/or technical supervisor require corrective action and documentation on unacceptable quality control and proficiency testing results.

7. The laboratory director, technical consultant, and/or technical supervisor evaluate the test results that appear inconsistent with clinically relevant criteria.

8. The laboratory director, technical consultant, and/or technical supervisor discuss with the staff any issues that have been identified.

**Standard LD.04.05.09**
The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

**Elements of Performance for LD.04.05.09**

1. Laboratory procedures are current and complete. *(See also DC.02.01.01, EP 1)*

2. The laboratory director signs and dates new laboratory procedures or changes in laboratory procedures before they are implemented. *(See also DC.02.01.01, EP 1; QSA.02.04.01, EP 7)*
3. The laboratory director requires that policies and procedures be consistently implemented and maintained.

4. Policies and procedures are readily available in writing to staff who do any kind of work for the laboratory, which includes collecting specimens and reporting test procedures.

5. Satisfactory specimen criteria are established, as are the limitations on the reliability of test results if the specimen is not satisfactory.

6. The laboratory director requires that test results be accurately reported within a defined time frame.

7. The laboratory director and/or clinical consultant require that results be reported with pertinent information as required for specific patient interpretation.

8. The laboratory director develops a process for clinical staff to request and receive test results on an emergency or stat basis.

9. The laboratory director develops criteria for notifying the responsible practitioner when critical limits or specified test results are exceeded.

10. The laboratory director or designee reviews, approves, and documents approval of each laboratory procedure every two years. (See also DC.02.01.01, EP 1)

**Standard LD.04.05.11**

The laboratory director is responsible for requiring laboratory practices that respect the needs of patients or other customers.

**Elements of Performance for LD.04.05.11**

1. The laboratory director is responsible for requiring laboratory practices that respect individual privacy and security.

2. The laboratory director is responsible for requiring laboratory practices that respect the patient’s or customer’s right to voice complaints about care or service and to have those complaints reviewed and, when possible, resolved.

3. The laboratory director is responsible for requiring laboratory practices that respect the patient’s or customer’s right to effective communication; this includes the rights of the hearing and speech impaired.
4. The laboratory director is responsible for requiring laboratory practices that respect the patient’s or customer’s right to confidentiality of information. (Refer to the “Information Management” (IM) chapter.)

5. The laboratory documents all complaints reported to the laboratory.

**Standard LD.04.05.13**

The laboratory director recommends reference laboratory services to the clinical staff for acceptance through the clinical staff’s designated mechanism.

**Elements of Performance for LD.04.05.13**

1. The laboratory director provides a written recommendation to the clinical staff for reference laboratory services (including outside services that provide blood and blood components).

2. The clinical staff is involved in selecting reference laboratory services, and the laboratory’s approval of those services is documented.

**Standard LD.04.05.15**

Responsibility for administrative direction and clinical direction is defined in writing.

**Note:** *The laboratory director is responsible for the overall operation and administration of the laboratory.*

**Elements of Performance for LD.04.05.15**

1. The responsibility for the laboratory’s administrative direction is defined in writing.

2. The responsibility for the laboratory’s clinical direction is defined in writing.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

What is included on your organization chart, and where is it located? (LD.01.01.01)

| TIP: Review the organization chart annually. Verify that names and titles are accurate and that the chart correctly identifies reporting lines and responsibilities. Be sure that staff know where it is located and can refer to it. |

Under what time frames, as defined by the organization, do leaders evaluate the following issues, and when was the last time each was evaluated? (LD.02.03.01)

- Performance improvement activities
- Reported safety and quality issues
- Proposed solutions and their impact on the organization’s resources
- Reports on key quality measures and safety indicators
- Safety and quality issues specific to the population served
- Input from the population served

When the organization has a new leader (member of the governing body, professional advisory committee, or director), what type of information is given to him or her during orientation to the organization? (LD.01.07.01)
**TIP:** Leaders should become thoroughly familiar with the concept and implication of safety and quality culture with regular communication with each other and to all staff.

What expectations have been set by leadership for using data collected from patients to improve safety and quality of care? What safeguards have been put in place to ensure the data is secure and unadulterated? (LD.03.01.01, LD.03.02.01)

How do leaders communicate and follow up on recommendations from external authorized agencies such as accreditation, certification, and regulatory bodies (i.e., follow-up requirement on unsuccessful proficiency testing results)? (LD.04.01.01)

When do state and local licenses and registrations (including CLIA waiver certificate) need to be renewed? (LD.04.01.01)

**TIP:** Create a log of all CLIA certificates with the corresponding specialties, subspecialties, certificate’s expiration, directorship, and renewal date.

Has the contract process been evaluated for all contracted services? (LD.04.03.09)
**TIP:** Incorporate data that are relevant to contract evaluations in the performance improvement (PI) program. This will streamline the data collection efforts to simultaneously support both processes.

What are the most recent performance improvement initiatives in the laboratory and how is the effectiveness being measured? (LD.04.04.01)

What actions, if any, were taken to resolve all identified safety issues? (LD.04.04.05)

What is the laboratory director’s scope of responsibilities? (LD.04.05.01, LD.04.05.03)

**TIP:** Document laboratory director’s specific job description pertaining to:
- Maintaining staff qualifications and competence
- Staff orientation, education, and training
- Establishment of laboratory policies and procedures
- Administrative responsibilities with laboratory operation
## Written Documentation Checklist

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

### Leadership (LD)

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD.01.01.01, EP 6</td>
<td>The laboratory has a written organizational plan or chart that delineates staff reporting relationships.</td>
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<tr>
<td></td>
<td>LD.01.03.01, EP 1</td>
<td>For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance defines in writing its responsibilities.</td>
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<tr>
<td></td>
<td>LD.01.03.01, EP 3</td>
<td>For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance approves the laboratory’s written scope of services.</td>
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<tr>
<td></td>
<td>LD.03.01.01, EP 4</td>
<td>Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.</td>
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<tr>
<td></td>
<td>LD.04.01.01, EP 1</td>
<td>The laboratory is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the services for which the laboratory is seeking accreditation from The Joint Commission.*</td>
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</table>

*Note 1: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.*

*Note 2: Each laboratory must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state law.*
* For more information on how to obtain a CLIA certificate, see http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)

<table>
<thead>
<tr>
<th>LD.04.01.01, EP 4</th>
<th>Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD.04.02.01, EP 1</td>
<td>The leaders define conflict of interest involving licensed independent practitioners or staff. This definition is in writing.</td>
</tr>
<tr>
<td>LD.04.02.01, EP 2</td>
<td>The leaders develop a written policy that defines how the laboratory will address conflicts of interest involving licensed independent practitioners and/or staff.</td>
</tr>
<tr>
<td>LD.04.03.09, EP 2</td>
<td>The laboratory describes, in writing, the nature and scope of services provided through contractual agreements. Note: A written agreement (such as a formal contract) is not required for reference laboratories; however, it is required for a contractual agreement in which a major portion of laboratory testing is provided by an outside laboratory.</td>
</tr>
<tr>
<td>LD.04.03.09, EP 3</td>
<td>Designated leaders approve contractual agreements.</td>
</tr>
<tr>
<td>LD.04.03.09, EP 5</td>
<td>Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services. Note: A written description of the expectations can be provided either as part of the written agreement or in addition to it.</td>
</tr>
<tr>
<td>LD.04.03.09, EP 10</td>
<td>Reference and contract laboratory services meet the federal regulations for clinical laboratories and maintain evidence of the same.</td>
</tr>
<tr>
<td>LD.04.05.09, EP 10</td>
<td>The laboratory director or designee reviews, approves, and documents approval of each laboratory procedure every two years. (See also DC.02.01.01, EP 1)</td>
</tr>
<tr>
<td>LD.04.05.11, EP 5</td>
<td>The laboratory documents all complaints reported to the laboratory.</td>
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<tr>
<td>LD.04.05.13, EP 1</td>
<td>The laboratory director provides a written recommendation to the clinical staff for reference laboratory services (including outside services that provide blood and blood components).</td>
</tr>
<tr>
<td>LD.04.05.13, EP 2</td>
<td>The clinical staff is involved in selecting reference laboratory services, and the laboratory's approval of those services is documented.</td>
</tr>
<tr>
<td>LD.04.05.15, EP 1</td>
<td>The responsibility for the laboratory’s administrative direction is defined in writing.</td>
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<tr>
<td>LD.04.05.15, EP 2</td>
<td>The responsibility for the laboratory’s clinical direction is defined in writing.</td>
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</tbody>
</table>
**Action Planning Tool**

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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<tr>
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**Leadership**

CAMLAB, January 2018
Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
National Patient Safety Goals (NPSG)

Chapter Outline

National Patient Safety Goals

I. Goal 1—Improve the accuracy of patient identification.
   A. Use of Two Patient Identifiers (NPSG.01.01.01)

II. Goal 2—Improve the effectiveness of communication among caregivers.
    A. Timely Reporting of Critical Results of Tests (NPSG.02.03.01)

III. Goal 7—Reduce the risk of health care–associated infections.
    A. Meeting Hand Hygiene Guidelines (NPSG.07.01.01)
Requirements, Rationales, and Elements of Performance

Goal 1
Improve the accuracy of patient identification.

**NPSG.01.01.01**
Use at least two patient identifiers when providing laboratory services.

**Rationale for NPSG.01.01.01**
Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual’s name, an assigned identification number, telephone number, or other person-specific identifier.

**Elements of Performance for NPSG.01.01.01**

1. Use at least two patient identifiers when administering blood or blood components; when collecting blood samples and other specimens for clinical testing; and when providing other treatments or procedures. The patient’s room number or physical location is not used as an identifier.  

   **Note:** An example of “other procedures” includes bone marrow aspirates.

2. Label containers used for blood and other specimens in the presence of the patient.

Goal 2
Improve the effectiveness of communication among caregivers.

**NPSG.02.03.01**
Report critical results of tests and diagnostic procedures on a timely basis.

**Rationale for NPSG.02.03.01**
Critical results of tests and diagnostic procedures fall significantly outside the normal range and may indicate a life-threatening situation. The objective is to provide the responsible licensed caregiver these results within an established time frame so that the patient can be promptly treated.
Elements of Performance for NPSG.02.03.01

1. Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:
   - The definition of critical results of tests and diagnostic procedures
   - By whom and to whom critical results of tests and diagnostic procedures are reported
   - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures

2. Implement the procedures for managing the critical results of tests and diagnostic procedures.

3. Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.

Goal 7
Reduce the risk of health care–associated infections.

NPSG.07.01.01
Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

Rationale for NPSG.07.01.01
According to the Centers for Disease Control and Prevention, each year, millions of people acquire an infection while receiving care, treatment, or services in a health care organization. Consequently, health care–associated infections (HAIs) are a patient safety issue affecting all types of health care organizations. One of the most important ways to address HAIs is by improving the hand hygiene of health care staff. Compliance with the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) hand hygiene guidelines will reduce the transmission of infectious agents by staff to patients, thereby decreasing the incidence of HAIs. To ensure compliance with this National Patient Safety Goal, an organization should assess its compliance with the CDC and/or WHO guidelines through a comprehensive program that provides a hand hygiene policy, fosters a culture of hand hygiene, and monitors compliance and provides feedback.
Elements of Performance for NPSG.07.01.01

1. Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) or the current World Health Organization (WHO) hand hygiene guidelines. *(See also IC.01.04.01, EP 1)*

2. Set goals for improving compliance with hand hygiene guidelines. *(See also IC.03.01.01, EP 1)*

3. Improve compliance with hand hygiene guidelines based on established goals.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

What scenarios require the use of at least two patient identifiers? (NPSG.01.01.01)

What is the laboratory’s time frame requirement for reporting critical patient results? (NPSG.02.03.01)

**TIP:** Create a log of specified time frame and notification protocol for each laboratory test’s critical results.

What set of hand hygiene guidelines has the laboratory implemented with staff? (NPSG.07.01.01)

**TIP:** Be prepared to discuss the laboratory’s hand hygiene program, the goals set for improvement, and how hand hygiene is monitored.
**Written Documentation Checklist**

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

<table>
<thead>
<tr>
<th>National Patient Safety Goal (NPSG)</th>
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<td>√ Standard and EP</td>
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| NPSG.02.03.01, EP 1 | Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:  
- The definition of critical results of tests and diagnostic procedures  
- By whom and to whom critical results of tests and diagnostic procedures are reported  
- The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures | |
### Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
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Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
Performance Improvement (PI)

Overview
All laboratories want better patient outcomes and, therefore, are concerned about improving the safety and quality of the laboratory services they provide. The best way to achieve this is by first measuring the performance of processes that support laboratory services and then by using that data to make improvements. The standards in this chapter stress the importance of using data to influence positive change.

About This Chapter
Leaders have responsibility for performance improvement. They set performance improvement priorities and provide the resources needed to achieve improvement. They make sure that all individuals who work in the laboratory participate in performance improvement activities. The leaders’ responsibilities are more fully described in the “Leadership” (LD) chapter. (Standards LD.03.01.01 through LD.03.06.01 describe the management of important laboratorywide systems that support safety and quality. Standard LD.04.04.01 addresses the need for leaders to establish performance improvement priorities.)

Collecting data is the foundation of performance improvement (See Standard IM.01.01.01 for managing information and Standard IM.02.02.03 for retrieving, disseminating, and transmitting health information in usable formats). Based on its setting, scope, and services, the laboratory selects measures that are meaningful to the laboratory and that address the needs of the patients it serves. In addition, The Joint Commission has identified important processes (see Standard PI.01.01.01) that should always be measured because they involve risk and can harm patients.

Regardless of how much data the laboratory collects, data are not useful if they are not analyzed. Analysis identifies trends, patterns, and performance levels that suggest opportunities for improvement. The laboratory can then make improvements based on the analysis. Of course, there is always the chance that analysis may reveal that more opportunities for improvement exist than a laboratory can manage at one time. In this case, leaders need to set priorities for improvement.
After a change has been made, the laboratory monitors that change by collecting and analyzing data to make sure the desired improvement is achieved and sustained. Laboratories should identify the results that will signify sustained improvement. If the improvement does not meet expectations, the laboratory makes additional changes, and the cycle starts again. These principles of performance improvement also apply whenever the laboratory wants to design new processes, such as a new service or an information management system (see Standard LD.04.04.03).

The standards in this chapter address the fundamental principles of performance improvement: collecting data, analyzing data, and taking action to improve.
Chapter Outline

I. Data Collection (PI.01.01.01)

II. Data Analysis (PI.02.01.01)

III. Performance Improvement (PI.03.01.01)
Standards, Rationales, and Elements of Performance

Introduction to Standard PI.01.01.01
Data provide organizations with important information that can be used in a variety of ways. Collecting and analyzing data on performance, outcomes, and other activities can help a laboratory assess its ability to provide quality services. Laboratories can collect data from many areas, including internal data obtained from staff, patients, records, and pre- and postanalytic phases of laboratory testing. Data are also available from quality control, risk management activities, and research studies. Other valuable data can be obtained from external sources such as regulators, insurers, and the community. In addition, laboratories should establish data collection priorities particular to their needs.

Note: The laboratory also collects data on quality control processes, analytic processes, and infection control. Standards addressing this data collection are located in the “Quality System Assessment for Nonwaived Testing” (QSA), “Environment of Care” (EC), and “Infection Prevention and Control” (IC) chapters.

Standard PI.01.01.01
The laboratory collects data to monitor its performance.

Elements of Performance for PI.01.01.01

1. The laboratory leaders set priorities for data collection. (See also LD.04.04.01, EP 1)

2. The laboratory identifies the frequency for data collection.

The laboratory collects data on the following:

3. Performance improvement priorities identified by laboratory leaders. (See also LD.04.04.01, EP 1)

7. The use of blood and blood components. (See also LD.04.04.01, EP 2)

8. All confirmed transfusion reactions. (See also LD.04.04.01, EP 2)

16. Patient perception of the safety and quality of laboratory services.
Note: The laboratory can use the hospital’s patient satisfaction survey as long as it addresses laboratory services.

22. Processes or outcomes related to patient preparation, including the provision of patient instructions and preparatory steps for the procedures.

23. Processes or outcomes related to handling specimens, including specimen collection, labeling, preservation, transportation, and rejection. (See also LD.04.04.01, EP 2)

24. Processes or outcomes related to communication processes, including efficient transfer of information, completeness of test requisition, timeliness of reporting results, and accuracy of reports.

25. The laboratory collects data to determine whether tests it offers meet the needs of the clinical staff and the population served.

Note: Data needed to support the review process may include age, disability groups, diagnoses, problems, levels of care, and treatment.

26. To support the review of clinician practices, the laboratory collects data on test utilization.

Introduction to Standard PI.02.01.01

When data are collected, they are analyzed using statistical tools and techniques. When the laboratory analyzes data over time, it transforms raw data into useful information. Analysis of data from internal sources allows the laboratory to identify patterns and trends and to monitor its performance. The laboratory may also have access to external databases that allow it to compare its performance with other laboratories on a specific topic, such as a procedure or outcome.

Standard PI.02.01.01

The laboratory compiles and analyzes data.

Elements of Performance for PI.02.01.01

3. The laboratory uses statistical tools and techniques to analyze and display data.

4. The laboratory analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
5. The laboratory compares data with external sources, when available.

   **Note:** Examples of external sources of information include the following:
   - Recent scientific, clinical, and management literature, including Sentinel Event Alerts
   - Practice guidelines or parameters
   - Performance measures
   - Reference databases
   - Other organizations with similar processes and standards that are periodically reviewed and revised

8. The laboratory uses the results of data analysis to identify improvement opportunities. *(See also LD.03.02.01, EP 5)*

**Standard PI.03.01.01**

The laboratory improves performance.

**Elements of Performance for PI.03.01.01**

2. The laboratory takes action on improvement priorities.

4. The laboratory takes action when it does not achieve or sustain planned improvements.

5. The laboratory develops and maintains a quality management system that directs and controls its quality improvement activities.*

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* Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document GP26 (Quality Management System: A Model for Laboratory Services).
Prompts to Assess Your Compliance

**Please note:** Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

Have performance monitoring data been collected and prioritized as identified by laboratory leaders? (PI.01.01.01)

**TIP:** Evaluate current initiatives to identify projects that qualify as performance improvement projects. If a team is currently working on solving a problem, collect data on the issue and use that to track improvement.

**TIP:** Review required data for collection and outline performance improvement initiatives as needed.

How often does the laboratory perform data analysis? (PI.02.01.01)

Does the laboratory continue to track and monitor to see if the implemented change has improved the process? (PI.03.01.01)

Is the laboratory collecting patient satisfaction data and using the results to improve performance? (PI.03.01.01)
Action Planning Tool

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Quality System Assessment for Nonwaived Testing (QSA)

Overview
The goal of quality systems assessment for nonwaived testing is to guide laboratories in achieving accuracy in testing. The requirements in this chapter address processes and activities that help to produce test results that are meaningful, reproducible, useful, valid, dependable, and specific to the needs of the population served. Because the requirements touch on all aspects of quality systems assessment, everyone who works in the laboratory will have a role in supporting the quality systems and thereby helping to produce the best possible results and outcomes.

Numerous resources are available to provide detailed technical guidance, such as resources from the Clinical and Laboratory Standards Institute (CLSI) and the AABB Technical Manual. Laboratories are encouraged to take advantage of the information that is available from these resources.

About This Chapter
The standards in this chapter outline policies and procedures that produce quality nonwaived test results. Standards that apply to proficiency testing and general quality control testing appear first, followed by standards that apply to specialties and subspecialties. “Specialty” and “subspecialty,” as used in this chapter, refer to units of the laboratory, whether the unit is called a department, a discipline, an area, a service, or a section. Please see the “Waived Testing” (WT) chapter for standards specific to that classification of tests.
Chapter Outline

I. Proficiency Testing
   A. Participation in Proficiency Testing Program (QSA.01.01.01)
   B. Maintaining Records of Participation (QSA.01.02.01)
   C. Handling and Testing of Proficiency Testing Samples (QSA.01.03.01)
   D. Independent Performance of Proficiency Testing (QSA.01.04.01)
   E. Nonregulated Analytes and Regulated Analytes for which Compatible Proficiency Testing Samples are Not Available (QSA.01.05.01)

II. Quality Control
   A. Establishing Quality Control Procedures through Test, Method, and Instrument Validation (QSA.02.01.01)
   B. Calibration and Recalibration (QSA.02.02.01)
   C. Calibration Verification (QSA.02.03.01)
   D. Individualized Quality Control Plan (QSA.02.04.01)
   E. Specialty and Subspecialty Quality Control Policies (QSA.02.06.01)
   F. Quality Control Ranges with Valid Statistical Measurements (QSA.02.07.01)
   G. Correlation to Evaluate Same Test Performed with Different Methodologies or Instruments or at Different Locations (QSA.02.08.01)
   H. Quality Control Testing in the Same Manner as Patient Testing (QSA.02.09.01)
   I. Monitoring the Accuracy and Precision of the Analytic Process (QSA.02.10.01, QSA.02.10.03)
   J. Surveillance of Patient Results (QSA.02.11.01)
   K. Investigation and Corrective Action (QSA.02.12.01)
   L. Reagent Storage, Preparation, Evaluation, and Tracking (QSA.02.13.01)
   M. Reagent and Solution Labeling (QSA.02.14.01)

III. Autopsy Services
   A. Performance and Supervision of Autopsy (QSA.03.01.01)
   B. Cadaver Storage and Preservation (QSA.03.02.01)
   C. Patient’s Clinical Record Includes Autopsy Results (QSA.03.03.01)

IV. Bacteriology, Mycobacteriology, and Mycology
   A. Testing of Chemical and Biological Solutions, Reagents, and Antisera (QSA.04.01.01)
   B. Verification of Antibacterial, Antimycobacterial, and Antifungal Susceptibility Testing Systems (QSA.04.02.01)
   C. Quality Controls for Stains (QSA.04.03.01)
   D. Testing of Microbiological Culture Media (QSA.04.04.01)
   E. Equipment (QSA.04.05.01)
   F. Identification Methods (QSA.04.06.01)
   G. Blood Cultures (QSA.04.07.01)
V. Blood Transfusion Service and Donor Center
   A. Blood Transfusion Service (QSA.05.01.01)
   B. Supplying Blood and Blood Components
      1. Blood and Blood Component Supply (QSA.05.02.01)
      2. Maintaining Blood and Blood Components for Emergencies
         (QSA.05.02.03)
      3. Releasing Blood and Blood Components to the Blood Supplier or Another
         Organization (QSA.05.02.05)
   C. Inspecting and Returning Blood and Blood Components
      1. Blood and Blood Component Inspection (QSA.05.03.01)
      2. Returning Unused Blood or Blood Components (QSA.05.03.03)
   D. Maintaining and Monitoring Temperature
      1. Temperature Ranges for Blood and Blood Components (QSA.05.04.01)
      2. Alarm Systems (QSA.05.04.03)
   E. Sera, Antisera, Cells, and Reagents (QSA.05.05.01)
   F. Reactivity Testing for Reagents (QSA.05.06.01)
   G. Blood Collection Labeling (QSA.05.07.01)
   H. ABO Group and Rh Type (QSA.05.08.01)
   I. Serologic and Computer Compatibility Testing
      1. Compatibility Testing (QSA.05.09.01)
      2. Validation of Computer Systems (QSA.05.09.03)
   J. Identification of Donor and Recipient Blood (QSA.05.10.01)
   K. Testing Performed Before Blood Administration (QSA.05.11.01)
   L. Sample Retention for Transfused Blood (QSA.05.12.01)
   M. Rh Immune Globulin Administration (QSA.05.13.01)
   N. Modification, Irradiation, and leukoreduction of Blood and Blood
      Components
      1. Modification of Blood and Blood Components (QSA.05.14.01)
      2. Plasma Products (QSA.05.14.03)
      3. Irradiation of Blood and Blood Components (QSA.05.14.05)
      4. Leukoreduced Blood and Blood Components (QSA.05.14.07)
   O. Platelet Products (QSA.05.16.01)
   P. Transfusion Related Activities (QSA.05.17.01)
   Q. Monitoring and Evaluation of Patients and Reporting of Suspected
      Transfusion-Related Adverse Events (QSA.05.18.01)
   R. Reporting, Investigating, and Interpreting Suspected Transfusion-Related
      Adverse Events
      1. Reporting and Investigating Suspected Transfusion-Related Adverse
         Events (QSA.05.19.01)
      2. Suspected Transfusion-Related Adverse Events Investigation
         (QSA.05.19.03)
      3. Suspected Transfusion-Related Adverse Events Interpretation
         (QSA.05.19.05)
S. Identification of Recipients Potentially Infected with Human Immunodeficiency Virus (HIV) (QSA.05.20.01)
T. Identification of Recipients Potentially Infected with Hepatitis C Virus (HCV) (QSA.05.21.01)
U. Record Retention (QSA.05.22.01)
V. Blood Donation (QSA.05.23.01)
W. Blood Donor Communication and Collection
   1. Blood Donor (QSA.05.24.01)
   2. Safe Collection, Handling, Processing, Testing, and Labeling of Blood and Blood Components (QSA.05.24.03)
X. Therapeutic Apheresis (QSA.05.25.01)

VI. Clinical Chemistry
A. Quality Control Testing (QSA.06.01.01)
B. Blood Gas Quality Control Testing (QSA.06.02.01)
C. Maternal Marker Screening (QSA.06.03.01, QSA.06.03.03)
D. Chromatography (QSA.06.04.01, QSA.06.04.03, QSA.06.04.05)

VII. Clinical Microscopy
A. Specimen Criteria (QSA.07.01.01)
B. Microscopic Examination of Urine Sediment (QSA.07.02.01)

VIII. Cytology
A. Staff Qualifications and Number (QSA.08.01.01)
B. Specimen Testing (QSA.08.02.01)
C. Quality Improvement Process (QSA.08.03.01)
D. Workload Limits (QSA.08.04.01)
E. Staining (QSA.08.05.01)
F. Quality Assurance System (QSA.08.06.01, QSA.08.06.03)
G. Slide Review (QSA.08.07.01)
H. Reporting (QSA.08.08.01)
I. Slide Maintenance, Storage, and Retrieval (QSA.08.09.01)

IX. Cytogenetics
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B. Sample Identification (QSA.09.02.01)
C. Quality Control and Testing Procedures (QSA.09.03.01, QSA.09.03.03, QSA.09.03.05, QSA.09.03.07)
D. Stages of Testing and Results (QSA.09.04.01)
E. Abnormal Case Retention (QSA.09.05.01)
F. Retention (QSA.09.06.01)
G. Result Reporting and Performance Monitoring (QSA.09.07.01, QSA.09.07.03)

X. Embryology
A. Testing Procedures (QSA.10.01.01)
B. Method Validation (QSA.10.02.01)
C. Record Maintenance (QSA.10.03.01)
D. Media Quality Controls (QSA.10.04.01)
E. Tracking (QSA.10.05.01)
F. Receipt and Transfer of Specimens (QSA.10.06.01)
G. Record Retention (QSA.10.07.01)

XI. Hematology and Coagulation
A. Procedure and Test Parameter Verification (QSA.11.01.01)
B. Coagulation Quality Control Testing (QSA.11.02.01)

XII. Histocompatibility
A. Quality Control Practices and Method Validation (QSA.12.01.01)
B. Recipient and Donor Crossmatching (QSA.12.02.01)
C. Human Leukocyte Antigen Serologic Typing (QSA.12.03.01)
D. Histocompatibility Testing (QSA.12.04.01)
E. Sera Screening (QSA.12.05.01)
F. Mixed Lymphocyte Cultures (QSA.12.06.01)
G. Interlaboratory Reproducibility Validation (QSA.12.07.01)

XIII. Histopathology
A. Specimen Submission and Exception (QSA.13.01.01)
B. Accompanying Information and Diagnoses (QSA.13.02.01)
C. Specimen Receipt, Identification, and Risk Management (QSA.13.03.01, QSA.13.03.03)
D. Specimen Examination (QSA.13.04.01)
E. Managing Electron Microscope Hazards (QSA.13.05.01)
F. Staining Quality (QSA.13.06.01)
G. Specimen Retention (QSA.13.07.01)
H. Surveillance Activities (QSA.13.08.01)

XIV. Immunology and Syphilis Serology
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B. Testing (QSA.14.02.01)

XV. Molecular Testing
A. Testing Policies and Procedures (QSA.15.01.01)
B. Verification Studies (QSA.15.02.01)
C. Quality Control Limits, Reference Ranges, and Reportable Ranges (QSA.15.03.01)
D. Quality Control Testing (QSA.15.04.01)
E. Reporting (QSA.15.05.01)

XVI. Molecular Genetics
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B. Reporting (QSA.16.02.01)
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   A. Reference Materials, Calibrated Measuring Device, and Reagents
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   B. Staining (QSA.17.02.01)

XVIII. Provider-Performed Microscopy (PPM) Procedures (QSA.18.01.01)

XIX. Radiobioassay
   A. Testing Procedures (QSA.19.01.01)
   B. Quality Control System (QSA.19.02.01)

XX. Semen Analysis (Andrology) (QSA.20.01.01)

XXI. Virology
   A. Testing Methodologies (QSA.21.01.01)
   B. Cell Controls and Processes (QSA.21.02.01)
   C. Record Maintenance (QSA.21.03.01)
   D. Serodiagnostic Tests (QSA.21.04.01)
Standards, Rationales, and Elements of Performance

**Introduction to Standards QSA.01.01.01 Through QSA.01.03.01**

Standards QSA.01.01.01 through QSA.01.03.01 apply to proficiency testing for regulated analytes. Proficiency testing is not required for nonregulated analytes; however, if the laboratory chooses to participate in a proficiency testing program for nonregulated analytes, these standards will also apply.

**Standard QSA.01.01.01**

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

**Note:** This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).

**Rationale for QSA.01.01.01**

Proficiency testing determines how well a laboratory’s results compare with those of other laboratories that use the same methodologies. Such testing can identify patterns of performance problems that may not be otherwise recognized by internal mechanisms (for example, quality control, preventive maintenance, competence evaluations).

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* For the current list of regulated analytes, refer to 42 CFR 493, Subpart H.
Elements of Performance for QSA.01.01.01

1. The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program\(^1\) that meets regulatory requirements for variety and frequency of testing.\(^2\) (See also LD.04.05.07, EP 4) \(^R\)

2. The laboratory authorizes the proficiency testing program to release all data required to determine the laboratory’s compliance for proficiency testing and makes proficiency testing results available to the public as required in the Public Health Service Act, Section 353(f)(3)(F). \(^R\)

3. The laboratory uses a proficiency testing program for each regulated analyte performed. \(^R\)

4. The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program before the conclusion of a full calendar year, it notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission before this change is made. \(^R\)

5. For each specialty, subspecialty, analyte, or test, the laboratory’s proficiency testing results meet satisfactory performance criteria in accordance with law and regulation. \(^R\)

Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), Subpart H, include the following:

- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing
- Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing

\(^1\) For information on current proficiency testing providers, see http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp.

\(^2\) For more information on proficiency testing, see http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.
• Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.

• Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.

Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.

(For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

6. The laboratory’s proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation. 

Note: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.

7. Individuals who examine gynecologic preparations participate in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing and satisfactory performance criteria.

Note 1: For an individual who fails an annual proficiency testing event (less than 90% on a 10-slide proficiency test), the laboratory schedules a retesting event that takes place not more than 45 days after the receipt of the notification of failure. Steps of retesting include the following:

• A 10-slide retest (event #2), performed within 2 hours, in which a score of 90% is acceptable.
For an individual who fails the 10-slide retest (event #2), the laboratory provides remedial training and education in the area of failure and has evidence that all patient gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide proficiency test (event #3), performed within 4 hours, in which a score of 90% is acceptable.

An individual who fails the last 20-slide proficiency test (event #3) ceases examining gynecologic slide preparations immediately upon notification of test failures and may not resume examining gynecologic slides until the laboratory has evidence that the individual obtained at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until the individual is retested with another 20-slide proficiency test and scores at least 90%.

This final cycle continues until the individual successfully participates in another 20-slide proficiency test.

Note 2: Unexcused absence by an individual for a retest will result in a test failure.

(See also QSA.01.02.01, EP 5)

Standard QSA.01.02.01

The laboratory maintains records of its participation in a proficiency testing program.

Rationale for QSA.01.02.01

The laboratory uses results outside acceptable ranges as an opportunity to correct problems, educate staff, prevent recurrence of problems, and improve the quality of services it provides.

Elements of Performance for QSA.01.02.01

1. The laboratory analyzes and reports results for each testing period during the two years prior to survey for accreditation by The Joint Commission.

   Note: The laboratory may consider retaining records for a minimum of five years to address potential Centers for Medicare & Medicaid Services (CMS)—required follow-up for repeated unsuccessful proficiency testing.

2. The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action for the following:
   - Individual unacceptable proficiency testing results
   - Late submission of proficiency testing results (score is zero)
   - Nonparticipation in the proficiency testing event (score is zero)
Lack of consensus among all laboratories participating in the proficiency testing event (score is ungradable)

These actions are documented. *(See also QSA.01.01.01, EP 5)*

**Note:** *This requirement also applies when the laboratory’s cumulative score for the event meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) requirements for satisfactory performance.*

3. The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.

4. The laboratory retains proficiency testing records for at least two years from the date of participation for the following proficiency testing events:
   - Each proficiency testing result
   - Test handling
   - Preparation
   - Processing
   - Examination
   - Each step in the testing
   - Signed attestation statement(s) provided by the proficiency program
   - A copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results
   - Corrective action taken

5. For cytology proficiency testing, the laboratory maintains records of acceptable testing performance, or documentation of retesting and corrective action, for individuals engaged in the examination of gynecologic preparations. *(See also QSA.01.01.01, EP 7)*

**Standard QSA.01.03.01**
The laboratory has a process for handling and testing proficiency testing samples.

**Elements of Performance for QSA.01.03.01**

1. The laboratory has written policies and procedures for testing proficiency testing samples.

2. The laboratory tests proficiency testing samples according to its policies and procedures.
3. The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate for each regulated analyte. (See also QSA.02.08.01, EP 1)

**Note:** Proficiency testing for secondary analyzers is not required.

4. Proficiency testing samples are tested along with the laboratory’s regular patient testing workload by staff who perform the laboratory’s testing.

5. The laboratory rotates proficiency testing samples among the staff who perform patient testing.

6. The laboratory’s staff tests the proficiency testing samples the same number of times that they test patient samples.

7. The laboratory staff who performed the proficiency testing along with the laboratory director sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens.

**Note:** The laboratory director may delegate this responsibility in writing to a technical consultant meeting the qualifications of 42 CFR 493.1409 (for moderate-complexity testing) or a technical supervisor meeting the qualifications of 42 CFR 493.1447 (for high-complexity testing).

**Standard QSA.01.04.01**

The laboratory performs its proficiency testing independent of other laboratories.

**Elements of Performance for QSA.01.04.01**

1. The laboratory does not send the proficiency testing samples to another laboratory for analysis. (See also APR.01.02.01, EP 1)

2. Communication between laboratories (interlaboratory and laboratories with multiple sites or separate locations) about the results of proficiency testing samples does not occur until after the date by which the laboratory must report proficiency testing results to the program for the testing event.

3. The laboratory notifies the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission of proficiency testing samples received from another laboratory for testing.
Standard QSA.01.05.01
The laboratory evaluates the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and regulated analytes for which compatible proficiency testing samples are not available.

Elements of Performance for QSA.01.05.01

1. ☐ The laboratory has written policies and procedures that include acceptability criteria to evaluate the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and regulated analytes for which compatible proficiency testing samples are not available. R

   Note: Acceptable methods of evaluating accuracy and reliability include the following:
   - Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)–certified reference laboratory for comparison with its own results.
   - Interlaboratory quality control results are used to evaluate the continuing accuracy and reliability of the tests not included in the proficiency testing program (for example, peer comparisons).
   - Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff member who performs such testing.
   - Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.

2. ☐ The laboratory performs verification testing at least every six months. The verification is documented. R

3. ☐ When performance verification is unacceptable, the laboratory performs an investigation of all potential causes, evidence of review, and corrective action sufficient to address and correct the issues identified in the investigation. These activities are documented. R

Standard QSA.02.01.01
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

Note: This standard also applies to instruments on loan when the original instrument is under repair.
Elements of Performance for QSA.02.01.01

1. When adding or replacing an unmodified US Food and Drug Administration (FDA)–approved test, method, or instrument, the laboratory verifies the manufacturer’s performance specifications, including the following:
   - Accuracy
   - Precision
   - Reportable range

   The verification is documented.

2. When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following:
   - Accuracy
   - Precision
   - Reportable range
   - Analytic sensitivity
   - Analytic specificity, including interfering substances

   Note: Modified tests, methods, or instruments include the following:
   - Test procedures with modifications to the US Food and Drug Administration (FDA)–approved use for specimen type, reagents, instrument, procedural steps, or other components
   - Tests or methods developed in the laboratory with no FDA evaluation
   - Tests, methods, or instruments not subject to FDA clearance

3. When replacing an old test, method, or instrument, the laboratory’s verification includes a correlation between the old and new test, method, or instrument. The correlation is documented.

   Note 1: This element of performance also applies when reference tests are brought in-house.

   Note 2: The laboratory has the discretion to determine the minimum number of data points and acceptable levels of correlation required for statistical validity and clinical usage of the test result.

4. For a new test, method, or instrument, the laboratory verifies that the reference intervals (normal ranges) apply to the test, method, or instrument and population served. The verification is documented.
5. The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented.

6. The laboratory’s verification includes the establishment of written quality control procedures for each testing system or methodology.

7. The laboratory’s quality control procedure for each testing system or methodology includes the following:
   - The range of quality control values used
   - The frequency of quality control testing
   - Adherence to the manufacturer’s recommendations
   - The predicted reliability based on history
   - The specialty and subspecialty requirements included in this chapter

   **Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

8. Over time, the laboratory monitors the accuracy and precision of test performance that may be influenced by changes in the following:
   - Test system performance
   - Environmental conditions
   - Variance in operator performance

**Standard QSA.02.02.01**
The laboratory performs calibration and recalibration.

**Rationale for QSA.02.02.01**
Calibration requirement and methods are based on manufacturer’s directions. Procedures that may be exempt from calibration requirements include manual procedures that do not use instrumentation, microscopic procedures, and procedures involving instruments that do not lend themselves to calibration.

**Elements of Performance for QSA.02.02.01**
1. The laboratory has a written procedure for calibration that includes, at a minimum, the following:
   - The requirements established by the instrument manufacturer
   - The number of calibration levels
The type of calibration materials used
- The concentration of the calibration materials
- The frequency of calibration
- The acceptable performance limits for the calibration

2. The laboratory performs calibration using materials traceable to a national reference standard, when available.

3. If quality control materials are used for calibration, the laboratory uses different lot numbers than those used for routine quality control testing.

4. The laboratory follows its procedure for calibration. The calibration performance is documented.

5. The laboratory recalibrates when indicated by evaluation of the following data:
- Calibration
- Calibration verification
- Quality control results
- Performance and function checks

The recalibration is documented. (See also EC.02.04.01, EP 3; QSA.02.11.01, EPs 1–7)

6. The laboratory has a written procedure for corrective action when calibration or control results fail to meet the laboratory’s criteria for acceptability. The corrective action is documented.

**Standard QSA.02.03.01**

The laboratory performs calibration verification.

**Elements of Performance for QSA.02.03.01**

1. The laboratory has a written procedure for calibration verification that includes the following, at a minimum:
- The requirements established by the instrument manufacturer
- The number of calibration verification levels
- The type of calibration verification materials used
- The concentration of the calibration verification materials
- The frequency of calibration verification
- The acceptable performance limits for the calibration verification
2. The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based on the manufacturer’s directions and instrument history.

**Note:** *The Joint Commission does not require the purchase of commercial linearity kits to meet this requirement. Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use for calibration verification.*

3. Calibration verification is performed every six months.

**Note 1:** *Semiannual calibration verification is not required when the laboratory performs calibration at least once every six months using three or more levels of calibration materials that include a low, mid, and high value.*

**Note 2:** *For automated cell counters, calibration verification requirements are met if the laboratory follows manufacturer’s instructions for instrument operation and the laboratory tests two levels of quality control materials each day of patient testing, provided the laboratory’s quality control criteria are met.*

**Note 3:** *Calibration verification is not required on instruments that are manufacturer-calibrated and/or tests that are considered non-quantitative. This exception only applies to those instruments that cannot be calibrated after implementation.*

4. Calibration verification is performed whenever the following events occur:
   - A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
   - Major preventive maintenance is performed, or critical parts are replaced that may influence test performance.
   - Quality control results indicate that there may be a problem with the test system.
   - An environmental change occurs, including instrument relocation.
   - An instrument has been replaced.
   - Quality control materials reflect an unusual trend or shift or are outside the laboratory’s acceptable limits, and other means of assessing and correcting unacceptable quality control values fail to identify and correct the problem.
5. The laboratory follows its procedure for calibration verification. The calibration verification performance is documented.

**Introduction to Standard QSA.02.04.01**

The Centers for Medicare & Medicaid Services (CMS) implemented a voluntary quality control option for clinical laboratories on January 1, 2016. The individualized quality control plan (IQCP) allows laboratories to customize quality control policies and procedures based on a risk assessment of their health care setting. IQCP applies to all specialties and subspecialties except pathology, and replaces the previous equivalent quality control (EQC) procedures.

There are additional requirements that are eligible for IQCP located in the QSA chapter of the *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing*. A list of all IQCP-eligible requirements is included in Appendix C: Individualized Quality Control Plan—Eligible Requirements, and the IQCP-eligible requirements can be filtered and displayed in the E-dition. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP-eligible Joint Commission accreditation requirements.

**Standard QSA.02.04.01**

The laboratory develops and implements an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

**Elements of Performance for QSA.02.04.01**

Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:

1. A complete IQCP that consists of the following three parts that the laboratory director signs and dates prior to implementation:
   - Risk assessment
   - Quality control plan
   - Quality assessment

2. A risk assessment that is established by the laboratory in its own environment by its own testing personnel.
Note: The risk assessment may include test, method, or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.

3. ⚫ A risk assessment that contains an evaluation of the following five components:
   - Specimen
   - Environment
   - Reagent
   - Test system
   - Testing personnel

4. ⚫ A risk assessment that encompasses the following three phases of the entire testing process:
   - Preanalytic
   - Analytic
   - Postanalytic

   Note: The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of error.

5. ⚫ A risk assessment that includes the manufacturer’s instructions or other information needed to assess risk in all three phases of the testing process.

   Note: The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers’ instructions.

6. ⚫ A quality control plan for devices at each location throughout a facility.

7. ⚫ A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation. (See also LD.04.05.09, EP 2)

8. ⚫ A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.

**Standard QSA.02.06.01**

Each laboratory specialty and subspecialty has a quality control policy.
Elements of Performance for QSA.02.06.01

1. ✅ A written quality control policy exists for each specialty and subspecialty offered as part of pathology and clinical laboratory services.

2. The quality control policy defines the number, type, and frequency of quality control materials according to the following:
   - Manufacturers’ recommendations
   - Performance specifications verified or established by the laboratory
   - Specialty and subspecialty requirements found in this chapter for quality control testing

   **Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

3. The quality control policy includes the quality control criteria for acceptability for each test.

4. The quality control policy includes acceptable quality control limits and reportable ranges for each test.

5. Quality control limits are strict enough to promote precision and accuracy for reliable patient test results.

6. Quality control limits and reportable ranges provide results with meaningful clinical applications.

   **Note 1:** Package insert quality control limits may be too wide to meet the elements of performance (EPs) for this standard. Quality control limits are based at least in part on laboratory-specific data, except as indicated in the EPs for standard QSA.02.07.01.

   **Note 2:** For manual tests that do not lend themselves to commercial quality control methods, alternative procedural controls with established limits may be used to verify the results. For example, manual reticulocyte counts could be verified by a specified percentage agreement of the results from two slides.

7. The laboratory’s quality control policy is accessible to staff.
Standard QSA.02.07.01

The laboratory has its own quality control ranges with valid statistical measurements for each procedure.

Elements of Performance for QSA.02.07.01

1. Before using control material for quality control purposes, the laboratory defines, in writing, control ranges for each lot number.

2. The laboratory determines through repetitive testing the statistical parameters for each lot number of control material, including mean, standard deviation, and coefficient of variation. The parameters are documented.

3. If the laboratory’s calculated control ranges reflect variance from previously established ranges, the laboratory investigates, resolves discrepancies, and provides the rationale for its decision.

4. The stated values of an assayed control material may be used as the target values, provided the stated values correspond to the methodology and instrumentation used by the laboratory and are verified by the laboratory through repetitive testing.

5. A manufacturer’s control range may be used if the laboratory can verify that the mean it obtained reflects the manufacturer’s mean. The verification is documented.

   **Note:** The laboratory may use values from package inserts only until it has established its own control ranges, or if the test is used so infrequently that calculations of valid statistics are not possible, or if a pattern of using package insert values does not exist.

6. A manufacturer’s control range may be used if the laboratory director determines, in writing, that the manufacturer’s range is narrow enough to provide results with meaningful clinical applications.

7. The laboratory establishes statistical parameters for unassayed control materials over time through concurrent testing of control materials with previously determined statistical parameters. The established statistical parameters are documented.

8. **For hematology and coagulation testing:** The laboratory generates statistics using the standard deviation of duplicate pairs when using patient samples as controls. The statistics are documented.
Note: Patient controls may be used to supplement the commercial controls if an acceptable level of precision has been defined.

Standard QSA.02.08.01

The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.

Elements of Performance for QSA.02.08.01

1. The laboratory has written policies and procedures to perform correlations between analytes when the same analytes are tested using different methodologies or instruments or at different locations. (See also QSA.01.03.01, EP 3)

Note 1: This element of performance is not applicable when both of the following criteria are met:
- Testing is performed under a separate Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate.
- The tests are used for a separate patient population (for example, blood gas analysis for patients throughout the hospital versus scalp pH analysis for neonates).

Note 2: Correlations are not required for test methods classified as waived procedures.

2. The laboratory performs correlations at least once every six months. The correlations are documented.

3. The laboratory defines the tolerance limits for agreement when performing comparisons of multiple instruments or different methods of the same test or assay.

4. The laboratory defines the target value and range of analytic values for which the control limits used are acceptable for multiple instrument comparison.

5. The laboratory informs the ordering practitioner of clinically significant differences in correlation results between analytes when the same analytes are tested using different methodologies or instruments or at different locations.

Standard QSA.02.09.01

The laboratory performs quality control testing in the same manner as it performs patient testing.
Elements of Performance for QSA.02.09.01
1. Only staff who perform patient testing perform quality control testing.
2. Staff who perform patient testing test quality control materials in the same manner as they test patient specimens.
3. The laboratory rotates quality control testing among staff who perform patient testing.
   
   **Note:** Not all staff are required to perform quality control testing each day they perform patient testing, but all staff are included in the quality control testing over time.

Standard QSA.02.10.01
The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

**Note:** This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires that the combination of controls and calibrators used each day of testing be rotated to check normal, alkalosis, and acidosis levels).

Elements of Performance for QSA.02.10.01
1. The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented.
2. The laboratory uses quality control materials at levels and a frequency consistent with manufacturers’ recommendations.
   
   **Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.
3. The laboratory uses two quality control materials of different concentrations for each quantitative procedure on each day the procedure is performed. The quality control results are documented.
4. The laboratory uses negative and positive control material for each qualitative procedure on each day the procedure is performed. The quality control results are documented.
5. The laboratory uses a negative and graded or titered positive reactivity control material for procedures that produce graded or titered results each day the procedure is performed. The quality control results are documented.

6. The laboratory uses a negative and positive reactivity control material to test staining materials for intended reactivity each day the procedure is performed. The quality control results are documented.

7. The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each day the procedure is performed. The quality control results are documented.

Note: For polymer-based immunohistochemical methods, a negative control is not required.

8. When direct antigen systems include an extraction phase, the laboratory uses two quality control materials, one of which is capable of detecting extraction errors. The quality control results are documented.

9. For each electrophoretic determination, the laboratory tests at least one quality control material containing the substances being identified or measured in patient testing. The quality control material is tested concurrent with patient specimens. The quality control result is documented.

10. For thin layer chromatography, each plate or card is spotted with a calibrator containing the substances or drug groups identified or reported by the laboratory. The calibrator includes at least one control material on each plate or card and is processed through each step of patient testing, including the extraction phase. The quality control result is documented.

11. If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented.

Note: Alternative quality control testing includes split sampling for testing by another method or in another laboratory or previously tested patient specimens tested in duplicate.

12. The laboratory does not report individual patient results unless quality control criteria are met.

13. The laboratory does not report individual patient results that exceed the reportable range.
14. ☐ The laboratory performs quality control testing before resuming patient testing when the following occurs:
   - A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and quality control results are not adversely affected by reagent lot number changes.
   - Major preventive maintenance or replacement of critical parts influences test performance.
   - After calibration in order to verify that the calibration protocol was successful.

   The quality control results are documented.

15. For quantitative tests, the laboratory tests quality control materials across the clinically significant values of the reportable test results during a 24-hour period.

16. ☐ A qualified\(^5\) individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment is documented.

**Standard QSA.02.10.03**

The laboratory uses positive control material to verify the performance of flow cytometry analyses.

**Elements of Performance for QSA.02.10.03**

1. ☐ The laboratory analyzes positive control material to verify the performance of reagents and staining procedures for flow cytometry methods at the following frequencies:
   - Each day of analysis for lymphocyte subset and CD34+ hematopoietic stem cell enumeration (single or dual platform) measurements
   - At least monthly for neoplastic hematolymphoid immunophenotyping

   The quality control results are documented. *(See also DC.02.01.05, EP 3)*

2. ☐ The laboratory selects the source of positive control material to verify the performance of reagents and staining procedures for flow cytometry methods according to the following criteria:

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External positive controls for lymphocyte subset and CD34+ hematopoietic stem cell quantitations
External and/or internal positive controls for neoplastic hematolymphoid cell immunophenotyping

The quality control results are documented.

**Note:** *External positive controls are normal patient or commercial controls. (See also DC.02.01.05, EP 3)*

3. The flow cytometry laboratory analyzes positive control material to verify the performance of reagents and staining procedures based on the application and method of analysis as follows:
   - Two levels of positive control for single platform measurements of CD4+ lymphocytes
   - Two levels of positive control for single platform measurements of CD34+ stem cell concentrations
   - Two levels of positive control for dual platform measurements of CD34+ stem cell concentrations
   - One level of positive control for dual platform measurements of CD4+ lymphocyte

   The quality control results are documented. *(See also DC.02.01.05, EP 3)*

4. The laboratory analyzes positive control material for single and dual platform flow cytometry quantitative tests at least daily or each time the flow cytometer is restarted. The quality control results are documented. *(See also DC.02.01.05, EP 3)*

**Standard QSA.02.11.01**

The laboratory conducts surveillance of patient results and related records as part of its quality control program.

**Elements of Performance for QSA.02.11.01**

1. The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following: R
   - Patient test results
   - Work records
   - Equipment performance testing records
   - Quality control results
2. The policies and procedures include criteria to determine acceptability of patient results before they are released. (See also QSA.02.02.01, EP 5)

3. The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented. (See also LD.04.05.01, EP 1; QSA.02.02.01, EP 5)

Note: Technical staff performing the review use specific criteria or computer algorithms to identify outlier results for manual review. Examples of criteria include the following:

- Unacceptable quality control results
- Test results that do not correlate with a patient’s known condition, age, sex, diagnosis, or pertinent clinical data; distribution of patient test results; and relationship with other test parameters
- Incongruent test results on one patient
- Abnormal test results
- Critical values

4. For high-complexity testing performed by trained high school graduates qualified under 42 CFR 493.1489(b)(5), the laboratory director, general supervisor, or technical supervisor reviews all results within 24 hours of patient testing. (See also QSA.02.02.01, EP 5)

5. The laboratory performs daily screening for errors in patient test results due to handwritten or manual data entry (for example, clerical errors). The daily screening is documented. (See also QSA.02.02.01, EP 5)

Note: Screening a sample of data is acceptable for compliance with this element of performance.

6. The laboratory performs screening for errors (for example, electronic transmission errors, formatting errors) in electronic and printed patient test results at a frequency defined by the laboratory. The screening is documented. (See also QSA.02.02.01, EP 5)

7. The laboratory performs review of other records (for example, work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented. (See also QSA.02.02.01, EP 5)
Standard QSA.02.12.01

The laboratory investigates and takes corrective action for deficiencies identified through quality control surveillance.

Elements of Performance for QSA.02.12.01

1. The laboratory has written policies and procedures to monitor, assess, and correct problems identified in the preanalytic, analytic, and postanalytic processes.

2. The laboratory’s policies and procedures include the identification of alternatives for providing patient testing, including backup systems and alternative facilities (for example, reference laboratories).

3. The laboratory follows its policies and procedures to monitor, assess, and correct problems identified in preanalytic, analytic, and postanalytic processes.

4. The laboratory performs corrective action when the following situations occur:
   - Quality control results do not meet the laboratory’s criteria for acceptability.
   - An instrument does not meet function check or performance testing requirements.
   - Incidents of incorrect test results are reported.
   - Patient test results are reported outside of the laboratory’s reportable range of test results.
   - Criteria for proper storage of reagents and specimens are not met.
   - Other incidents of unsatisfactory specimen collection, testing, or reporting are identified.

   The corrective action is documented.

5. For each quality control result outside acceptable limits, the laboratory conducts an investigation of all potential causes, provides evidence of review, and takes corrective action. These activities are documented.

6. For each quality control result outside acceptable limits, the laboratory takes corrective action before patient testing is resumed.

7. As part of the corrective action, the laboratory documents the following:
   - Related quality control results
   - Related repeat patient testing
   - Related correction of individual results
8. As part of the corrective action, the laboratory performs the following:
   - Review of the effectiveness of the corrective action
   - Revision of policies and procedures to prevent recurrence
   - Discussion of the investigation and corrective action with affected staff

9. ⚫ When the laboratory becomes aware of an incorrect test result, it notifies the authorized person ordering the test, and if different, the individual using the test results. The notification is documented. *(See also QSA.08.08.01, EPs 5 and 6)*

10. ⚫ The laboratory issues a written corrected report to the practitioner who ordered the test or will receive the results as soon as the patient test results become available.

11. As part of the corrective action, the laboratory retains an exact copy of the original and corrected paper or electronic reports.

**Standard QSA.02.13.01**
The laboratory stores, prepares, evaluates, and tracks reagents.

**Elements of Performance for QSA.02.13.01**

1. ⚫ The laboratory has written policies and procedures for storing, preparing, evaluating, and tracking reagents.

2. The laboratory stores reagents as described on the label or by the manufacturer.

   **Note:** *Reagents include, but are not limited to, quality control materials, calibration materials, standards, substrates, water, alcohols, diluents, and other test kit components.*

3. The laboratory reconstitutes reagents that are not prepackaged as indicated on the label or by the manufacturer.

4. ⚫ The laboratory evaluates kits, including reagents, standards, diluents, and other ancillary reagents. The evaluation is documented.

5. ⚫ The laboratory checks the following opened or prepared items for positive and negative reactivity, as well as graded reactivity, if necessary:
   - Each batch of reagents prepared in-house
   - Lot number and shipment of commercially prepared reagents
   - Disks
   - Stains
   - Antisera
Identification systems using two or more substrates or reagents, or a combination of substrates and reagents

The reactivities are documented.

6. The laboratory documents the lot numbers of reagents in a manner that permits tracking when specific reagents are in use.

7. The laboratory does not interchange components of reagent kits of different lot numbers unless permitted by the manufacturer.

8. The laboratory uses kits, reagents, media, and supplies according to manufacturers’ specifications. (See also QSA.02.14.01, EP 5)

9. The laboratory verifies that the water used meets the criteria for the test method and does not interfere with specificity, accuracy, or precision of the test (for example, culturing deionized or distilled water, verifying pH). The verification is documented.

Standard QSA.02.14.01

The laboratory labels reagents and solutions completely and accurately.

Elements of Performance for QSA.02.14.01

1. The laboratory has written policies and procedures for labeling reagents and solutions.

2. The policy for labeling reagents and solutions includes the following:
   - Identity
   - Strength
   - Titer
   - Concentration
   - Cautionary and accessory information
   - Preparation and expiration dates

3. The laboratory identifies reagents that could pose a hazard for staff safety.

   Note: For more information on hazardous materials and waste, please refer to the “Environment of Care” (EC) chapter, EC.02.02.01.

4. The laboratory does not use deteriorated or substandard reactivity materials.

5. The laboratory does not use expired reagents or solutions. (See also QSA.02.13.01, EP 8)
6. The laboratory follows its policies and procedures for labeling reagents and solutions.

**Standard QSA.03.01.01**

A pathologist or a qualified physician performs or supervises each autopsy.

*Note:* *This standard does not apply to autopsies conducted for forensic purposes only.*

**Elements of Performance for QSA.03.01.01**

1. Autopsies are performed by pathologists or physicians whose credential files document their qualifications in anatomic pathology, or by qualified individuals under the direct supervision of pathologists or qualified physicians. (If the pathologist is also serving as a laboratory director, *see also* HR.01.02.03, EP 1, for qualifications.)

2. A pathologist qualified in anatomic pathology makes all microscopic interpretations related to autopsies.

3. A pathologist prepares a diagnostic report of each autopsy performed.

**Standard QSA.03.02.01**

Refrigeration is available for the storage and preservation of cadavers.

**Rationale for QSA.03.02.01**

Laboratories located in facilities that manage the disposition of cadavers provide for storage. Refrigeration for cadavers can be provided within the organization or at a facility close to the organization (for example, a mortuary).

**Element of Performance for QSA.03.02.01**

1. The organization provides for refrigeration for cadaver storage and preservation.

**Standard QSA.03.03.01**

Clinical autopsy results performed within or outside the organization are included in the patient’s clinical record.

*Note:* *This standard does not apply to autopsies conducted for forensic purposes only.*

**Elements of Performance for QSA.03.03.01**

1. When a clinical autopsy is performed, provisional anatomic diagnoses are recorded in the patient’s clinical record within three days.
2. When a clinical autopsy is performed, the results (including a gross, microscopic, and final diagnostic report) are included in the patient’s clinical record within 60 days of the autopsy unless exceptions for special studies (for example, chromosome analysis) are established in writing by the clinical staff.

**Standard QSA.04.01.01**

The laboratory tests chemical and biological solutions, reagents, and antisera used in bacteriology, mycobacteriology, and mycology for reactivity and deterioration.

**Elements of Performance for QSA.04.01.01**

1. The laboratory tests and inspects chemical and biological solutions, reagents, and antisera used for identification of bacteria, mycobacteria, and fungi for deterioration.

2. The laboratory uses a positive and, as appropriate, a negative control material for each qualitative procedure in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented.

   **Note:** *A negative control is not required for the mycology germ tube test.*

3. The laboratory uses a positive control material with graded reactivity for procedures that produce graded results in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented.

4. The laboratory performs quality controls on biochemical panels at least once prior to or concurrent with patient testing for each new batch, lot, or shipment, and at a frequency that meets the manufacturer’s instructions, if more stringent. The quality control results are documented.

5. The laboratory performs quality controls each day the procedure is performed for deoxyribonucleic acid (DNA) probes, camp tests, and beta-lactamase methods other than the Cefinase brand method. The quality control results are documented.

6. The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened at a frequency consistent with laboratory policy, or manufacturer’s instructions if more stringent, for the following:
   - Bacitracin
   - Catalase
Quality System Assessment for Nonwaived Testing

- Coagulase plasma
- The Cefinase brand method
- Germ tube
- ONPG
- Optochin
- Oxidase
- Spot indole
- X, V, and XV factor discs or strips
- Yeast morphology media

The quality control results are documented.

**Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

7. ☑️ The laboratory performs quality controls for typing sera when prepared or opened and every six months thereafter or at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented.

**Standard QSA.04.02.01**

The laboratory verifies antibacterial, antymycobacterial, and antifungal susceptibility testing systems with approved reference organisms.

**Elements of Performance for QSA.04.02.01**

1. ☑️ Prior to reporting patient results, the laboratory performs quality control testing using approved reference organisms for each lot or shipment of antibacterial, antymycobacterial, and antifungal susceptibility testing agents. The quality control results are documented.

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2. The laboratory performs antibacterial and antifungal susceptibility quality control testing each day the procedure is performed unless the laboratory demonstrates satisfactory performance that would qualify the laboratory to perform quality control testing on a weekly basis. (For more information on developing an individualized quality control plan, refer to Standard QSA.02.04.01.) The quality control results are documented.

3. To sustain weekly quality control testing, for each nonobvious error, the laboratory retests the out-of-control antimicrobial agent/organism combination on the day the error occurred and performs daily quality control for a total of 5 consecutive patient test days. The activities are documented.

Note: If quality control is not sustained for a total of 5 days, then to requalify for weekly quality control, the laboratory documents that control strains were tested for a minimum of 20 to 30 consecutive test days for each antimicrobial agent/organism combination. No more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable range.

4. The laboratory performs antimycobacterial susceptibility quality control testing on a weekly basis, and on each new batch of media, and on each new lot number and shipment of antimycobacterial agent(s). The quality control results are documented.

Standard QSA.04.03.01
The laboratory uses quality controls to test stains in bacteriology, mycobacteriology, and mycology.

Elements of Performance for QSA.04.03.01

1. The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. The reactivity is documented.

The laboratory performs quality control testing on stains at the following frequencies:

2. With each new lot number and weekly for Gram stains. The quality control results are documented.

3. Concurrent with each staining procedure for staff who do not routinely perform Gram stains (for example, staff on call). The quality control results are documented.
4. Each day of use for nonfluorochrome acid-fast stains and special stains (for example, spore, capsule, flagella). The quality control results are documented.

5. Each time of use for fluorochrome acid-fast and other fluorescent stains. The quality control results are documented.

**Standard QSA.04.04.01**

The laboratory tests each type of microbiological culture media with selected organisms to confirm the required growth characteristics.

**Elements of Performance for QSA.04.04.01**

1. The laboratory has access to nationally accepted protocols for testing microbiological culture media, whether tests are performed by the user or preparer.

2. The laboratory documents its receipt of each microbiological culture media shipment and the condition of the following:
   - Cracks in the Petri dishes
   - Unequal filling of plates
   - Cracked media
   - Hemolysis
   - Freezing
   - Excessive number of bubbles
   - Contamination

3. The laboratory or the preparer performs quality control testing on new batches, lot numbers, and shipments of microbiological culture media, including sterility testing, using recommended organisms before or concurrently with the use of new batches of media. The quality control results are documented.

   **Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

4. The laboratory maintains documentation of microbiological culture media quality control results performed by the manufacturer if the laboratory does not retest before use.
5. The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms. The quality control results are documented.

6. The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented.

**Standard QSA.04.05.01**
The laboratory uses equipment that supports the recovery of bacteria, mycobacteria, and fungi.

**Elements of Performance for QSA.04.05.01**

1. If the laboratory incubates cultures in bacteriology, mycobacteriology, and mycology, it uses incubating equipment that supports the optimal temperature and atmospheric conditions (for example, aerobic, anaerobic, increased carbon dioxide conditions, temperature) for the recovery of the intended organisms.

2. The laboratory uses aerosol-free centrifuge equipment (for example, tubes, carriers, cups) for mycobacteriology procedures that require centrifugation.

**Standard QSA.04.06.01**
The laboratory has methods for the identification of bacteria, mycobacteria, and fungi.

**Elements of Performance for QSA.04.06.01**

1. The laboratory has written policies and procedures to isolate and identify bacteria, mycobacteria, and fungi from potential sites of infection that address the following:
   - Name of test(s) used
   - Type(s) of media required
   - Reagent(s) needed
   - Required confirmatory testing

2. The laboratory collaborates with the medical staff to develop policies and procedures for reporting antibiotic susceptibility patterns in organisms from potential sites of infection.

3. The laboratory reports the results of acid-fast stains, both positive and negative, within 24 hours of specimen receipt.

4. The laboratory maintains stock cultures of reference organisms.
5. The laboratory follows its policies and procedures to isolate and identify bacteria, mycobacteria, and fungi.

6. All stool specimens from patients diagnosed with acute community-acquired diarrhea are simultaneously cultured for O157 Shiga toxin-producing Escherichia coli (STEC) on selective and differential agar and assayed for non-O157 STEC with a test that detects Shiga toxins or the genes encoding these toxins.

**Standard QSA.04.07.01**

The laboratory has written policies and procedures for the collection, transport, processing, and interpretation of blood cultures.

**Rationale for QSA.04.07.01**

A blood culture is a specimen of blood submitted to the laboratory to detect the presence of microorganisms. A blood culture is the fundamental laboratory test used to diagnose sepsis or systemic inflammatory response syndrome (SIRS) plus infection. Rapid, accurate diagnosis of sepsis optimizes antimicrobial therapy, improves clinical outcomes, and reduces health care costs.

**Elements of Performance for QSA.04.07.01**

1. The laboratory defines the recommended volume of blood to be drawn for each blood culture. Definition is based on an approved clinical guideline, manufacturers’ requirements, and instrument specifications.

2. The laboratory’s processing of conventional (manual) blood cultures includes visual inspection for microbial growth (turbidity, growth of microcolonies, hemolysis, color changes, gas production):
   - After 12 to 24 hours of incubation at 35°C
   - Twice daily for days one and two
   - Daily for days three to seven

   The results are documented.

3. The laboratory establishes guidelines for the collection, transport, and processing of blood cultures to minimize contamination and support infection prevention and control activities.

* Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document M47 (Principles and Procedures for Blood Cultures).
**Standard QSA.05.01.01**

The laboratory has written policies and procedures for the blood transfusion service.

**Elements of Performance for QSA.05.01.01**

1. Ⓞ The laboratory has written policies and procedures for the blood transfusion service. R

2. The policies and procedures for the blood transfusion service are current and are revised whenever standards of practice change. R

3. The policies and procedures for the blood transfusion service are available to staff involved in transfusion services. R

4. Ⓞ The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology conducts a review of the policies and procedures of the blood transfusion service every two years. The review is documented. R

   **Note:** A designee is not permitted to conduct this review.

5. The transfusion service director has oversight of policies, processes, and procedures related to the blood transfusion service, including blood administration. R

6. The laboratory’s written policies and procedures for administration of outpatient transfusions include instructions for monitoring adverse patient reactions after release from direct medical observation. R

7. Ⓞ The transfusion service obtains written documentation of approval from the medical director when clinical situations warrant an exception to policies, processes, or procedures. R

8. The laboratory follows its policies and procedures for the blood transfusion service. R

9. Ⓞ The policies and procedures for the blood transfusion service define the staff responsible for the provision of blood, blood components, tissue, derivatives, and services.

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Standard QSA.05.02.01
A supply of blood and blood components that meets the needs of the patients, the services provided by the organization, and the clinical staff is available at all times to the organization.

Elements of Performance for QSA.05.02.01

1. The laboratory has written policies and procedures for maintaining a minimum inventory of blood and blood components.

2. The laboratory establishes a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff.

3. A written agreement with a blood supplier includes the following:
   - The responsibilities of both parties and approval by the transfusion service director or administrator
   - The process for procurement, transfer, and availability of blood and blood components if the laboratory itself does not provide blood banking services on site
   - The notification by the blood supplier to the laboratory’s transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV)

4. Transportation for the blood and blood components from the supplier is available.

5. The laboratory follows its policies and procedures for maintaining a minimum inventory of blood and blood components.

Standard QSA.05.02.03
The laboratory has policies and procedures for maintaining blood and blood components for emergencies.

Elements of Performance for QSA.05.02.03

1. The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.

2. Policies and procedures for obtaining blood or blood components needed in urgent or emergent situations address the following:
The minimum inventory of blood and blood components to be maintained by the blood bank
The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization

3. The laboratory follows its policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.

**Standard QSA.05.02.05**

For blood and blood components that will not be used within the organization, the laboratory has policies and procedures for releasing it to the blood supplier or another organization.

**Elements of Performance for QSA.05.02.05**

1. The laboratory has written policies and procedures for releasing blood and blood components to the blood supplier or another organization.
2. Policies and procedures for releasing blood and blood components to the blood supplier or another organization address the following:
   - How to determine the availability of blood and blood components for release
   - The agreement between the laboratory and the blood supplier for return and transfer of blood and blood components
   - The safe transport of blood and blood components
   - Record maintenance
3. The laboratory follows its policies and procedures for releasing blood and blood components to the blood supplier or another organization.

**Standard QSA.05.03.01**

The laboratory inspects received, stored, or issued blood or blood components for any abnormality in appearance.

**Elements of Performance for QSA.05.03.01**

1. The laboratory inspects received, stored, or issued blood or blood components for evidence of hemolysis and bacterial contamination. The inspection is documented.
2. If an abnormality is found, the blood or blood component is not used unless authorized by the transfusion service director.
Standard QSA.05.03.03
The laboratory has policies and procedures for returning unused blood and blood components previously issued for transfusion to the blood bank.

Elements of Performance for QSA.05.03.03
1. The laboratory has written policies and procedures for controlling transport, storage, and return of unused blood (including reissuance of returned blood) from other parts of the organization to the blood bank.

2. Policies and procedures for returning unused blood previously issued for transfusion to the blood bank address the following:
   - Temperature and time restriction
   - Requirements for intact labeling and intact ports on the blood unit
   - Storage, transport, and expiration of blood or blood components
   - Retention of documentation

3. The laboratory follows its policies and procedures for controlling transport, storage, or return of unused blood.

Standard QSA.05.04.01
The laboratory maintains temperature ranges for the safe storage and transport of blood and blood components.

Elements of Performance for QSA.05.04.01
1. The laboratory has procedures on temperature ranges for blood and blood components that include the following:
   - Whole blood and packed red cells: 1°C to 6°C
   - Frozen plasma: less than or equal to -18°C
   - Cryoprecipitated AHF: less than or equal to -18°C
   - Red cells frozen in 40% glycerol: less than or equal to -65°C
   - Red cells frozen in 20% glycerol: less than or equal to -120°C
   - Platelets: 20°C to 24°C
   - Granulocytes: 20°C to 24°C

†† Additional information on storage and transportation can be found in the current edition of the AABB’s Standards for Blood Banks and Transfusion Services, Table 5.1.8A.
‡‡ Additional information on storage and transportation can be found in the current edition of the AABB’s Standards for Blood Banks and Transfusion Services, Table 5.1.8A.
2. The laboratory maintains temperature ranges for the storage of blood and blood components.

3. The laboratory maintains temperature ranges for the transport of blood and blood components.

4. The laboratory records blood and blood components storage temperatures continuously or at least once every four hours. The temperatures of blood storage are documented.

**Standard QSA.05.04.03**

The laboratory uses alarm systems for refrigerators and freezers to monitor storage temperatures for blood and blood components.

**Elements of Performance for QSA.05.04.03**

1. The laboratory has alarm systems for each refrigerator or freezer that meet the following requirements:
   - Alarms are audible.
   - Remote alarms are present for use when staff are not in the immediate area.
   - Alarms, including remote alarms, are monitored continuously.
   - The alarm system is battery operated or powered by a different circuit than the refrigerator(s) and freezer(s).

2. The laboratory has written policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.

3. Policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers include the following:
   - A list of staff to notify, in order of priority
   - Backup or alternative provisions for blood storage
   - A process for maintaining records

4. The laboratory makes available to blood bank staff its policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.

5. The laboratory follows its policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.
Standard QSA.05.05.01
The laboratory uses sera, antisera, cells, and reagents of the same quality as federally licensed equivalents.

Elements of Performance for QSA.05.05.01
1. The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents.
2. The laboratory uses sera that meet federal licensing requirements or that are approved by the US Food and Drug Administration (FDA).
3. The laboratory uses antisera and reagent products that are licensed by the US Food and Drug Administration (FDA).
4. The laboratory uses other prepared reagents that meet or exceed US Food and Drug Administration (FDA) requirements.
5. If IgG-coated red cells and A and B cells used for reverse grouping are prepared locally, the laboratory tests for reactivity and specificity of those cells. The reactivity results and specificity are documented.
6. The laboratory follows its criteria for use of sera, antisera, cells, and reagents.

Standard QSA.05.06.01
The laboratory conducts reactivity testing on the potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations.

Elements of Performance for QSA.05.06.01
1. The laboratory has written policies and procedures for reagent reactivity testing.
2. Each day the procedure is performed, and when a new lot of reagents is first used, the laboratory tests at least one vial from each lot number of antisera, reactive cells, and reagents for reactivity. The reactivity results are documented.
   Note: This testing includes positive and negative reactivity when recommended by the manufacturer.
3. The laboratory confirms that each reagent reacts as expected. The confirmation is documented.
4. The laboratory retains a copy of manufacturers’ reagent package inserts. The date placed into service is documented.
5. The laboratory reviews manufacturers’ package inserts of reagent lots for changes in instructions for use prior to using reagent. The laboratory then updates procedures when instructions change.

6. The laboratory follows its policies and procedures for reactivity testing.

**Standard QSA.05.07.01**

The organization labels blood specimens drawn from a recipient for typing and crossmatching.

**Elements of Performance for QSA.05.07.01**

1. The organization has written policies and procedures addressing specimen collection for typing and crossmatching.

2. Policies and procedures addressing specimen collection for typing and crossmatching include the requirement that the recipient be positively identified at the time of collection using two unique identifiers (neither of which is the patient room number).

3. Policies and procedures addressing specimen collection for typing and crossmatching include the requirement to label specimens legibly and immediately upon collection, in the presence of the recipient.

4. The request forms and the specimen label for typing and crossmatching include the following:
   - The recipient’s full name
   - The unique identifying number
   - The specimen collection date

5. Policies and procedures addressing specimen collection for typing and crossmatching include a consistent approach to identify recipients who are unknown, incoherent, or unconscious.

6. The organization identifies the individuals who draw blood for typing and crossmatching.

7. The organization follows its policies and procedures addressing specimen collection for typing and crossmatching.

**Standard QSA.05.08.01**

The laboratory tests donor blood and recipient blood with potent typing sera and reactive cells of a known type to determine the correct ABO blood group and Rh type.
Elements of Performance for QSA.05.08.01

1. The laboratory has written policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type.

According to its policies and procedures, the transfusion service performing the crossmatch confirms the following:

2. The ABO group of all units of whole blood and red blood cell components.

   **Note:** The laboratory determines the ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents.

3. The Rh type of units labeled as Rh negative.

   **Note:** The laboratory determines the Rho(D) type by testing unknown red cells with anti-Rho (anti-D) blood typing reagent.

4. The ABO group and Rh type of the recipient.

   **Note:** For confirmation of the ABO group, the unknown serum is tested with known A1 and B red cells.

5. The Rho(D) negative donor cells are tested for the Du variant.

   **Note 1:** This test is performed by the donor center.

   **Note 2:** Confirmatory testing for the Du variant does not have to be completed by the transfusion service.

6. The laboratory follows its policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type.

Standard QSA.05.09.01

The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

Elements of Performance for QSA.05.09.01

1. The laboratory has written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood.

2. Policies and procedures for compatibility testing include the following:
   - A determination of recipient ABO Group and Rh type
   - A serologic and computer (if performed) crossmatch protocol
An antibody screening protocol
- Actions to be taken in cases of positive antibody screens and direct antiglobulin tests
- Actions to be taken in cases of incompatible crossmatches
- A time frame during which a sample may be used for crossmatching before obtaining a new sample
- A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

3. Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): Tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a compatibility test major crossmatch between donor red cells and recipient serum. 

Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required.

4. The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood for any blood products containing greater than 2 mL of red blood cells. The results are documented.

5. The laboratory compares current ABO group, Rh type, and antibody screen test results to historical results. Discrepancies are investigated and resolved prior to transfusion. The investigation is documented.

6. The laboratory’s method to screen for unexpected red cell alloantibodies includes the use of non-pooled reagent red cells and incubation at 37°C, followed by an antiglobulin (or equivalent) test.

7. The laboratory has a process in place to identify patients who require specially selected products based on both current admission orders and transfusion history (for example, irradiated, leukoreduced, antigen-negative units).

8. The laboratory employs a direct antiglobulin technique (DAT) capable of detecting immunoglobulin G (IgG) and complement components bound to red blood cells.
9. The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood. The results of this test are documented. 

**Standard QSA.05.09.03**

The laboratory validates computer systems used to detect ABO blood group incompatibility.

**Elements of Performance for QSA.05.09.03**

1. The laboratory defines system requirements before the validation of computer systems to detect ABO incompatibility. 

If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following:

2. On-site validation of selection limited to ABO compatible whole blood or red blood cells for transfusion. 

3. Confirmation of recipient ABO group by retesting the current sample, testing a second sample, or comparing results of current first drawn sample with previous records. 

4. The computer system record contains donor unit information including the identification number, component name, ABO group, and Rh type of the component. 

5. The computer system record contains recipient information including two patient identifiers, ABO group, Rh type, antibody screen results, and interpretation of compatibility. 

6. Verification of manual data entered into the computer system prior to release of blood or blood components. 

7. Generation of system alerts to notify user of discrepant serologic, labeling, or compatibility results of the donor unit or the recipient. 

8. The laboratory validates computer systems used for ABO incompatibility testing. The activities are documented. 

**Standard QSA.05.10.01**

The laboratory has policies and procedures for identifying donor blood and recipient blood.
Elements of Performance for QSA.05.10.01

1. The laboratory has written policies and procedures for identifying donor blood and recipient blood.  

2. Policies and procedures for identifying donor blood and recipient blood include the following:  
   - The blood recipient’s full name  
   - An additional patient identifier (for example, a clinical record number, health care account number)  
   - A protocol for labeling of donor blood and recipient blood, including securely affixing the label to the units after crossmatching and retention of the label on the units until the transfusion is completed  

3. The laboratory follows its policies and procedures for identifying donor blood and recipient blood.

Standard QSA.05.11.01

The laboratory has written policies and procedures for emergent release of blood.

Elements of Performance for QSA.05.11.01

1. The laboratory’s written policies and procedures for emergent release of blood address selection of blood and blood components when compatibility testing is incomplete.  

2. The laboratory obtains documentation justifying the release of uncrossmatched blood in an emergency situation. The clinician responsible for the recipient authenticates the documentation.  

3. The laboratory completes tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a major crossmatch between donor red cells and recipient serum as soon as possible. Abnormal results that may affect the patient’s safety are reported immediately by staff to the medical director and the clinician responsible for the patient’s care.  

   Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required. (For more information, refer to Standard QSA.05.09.01.)
4. The laboratory follows its procedures for emergent release of blood and components.

**Standard QSA.05.12.01**
The laboratory retains samples of each unit of transfused blood and a sample of recipient blood.

**Rationale for QSA.05.12.01**
The samples of each transfused unit and recipient blood are retained for further testing in the event of an adverse reaction.

**Elements of Performance for QSA.05.12.01**
1. The laboratory retains samples of transfused blood and a sample of recipient blood for at least 7 days following a transfusion and 10 days following a crossmatch.
2. The laboratory disposes of expired blood not needed for further testing.

**Standard QSA.05.13.01**
The laboratory has written policies and procedures that address Rh immune globulin (RhIG) administration.

**Elements of Performance for QSA.05.13.01**
1. The laboratory’s written policies and procedures for the administration of Rh immune globulin address:
   - Criteria to identify patients eligible for prophylaxis
   - Procedure to determine dose of RhIG required
   - Optimal timing of administration following exposure
2. The laboratory follows its policies and procedures for RhIG administration.

**Standard QSA.05.14.01**
The laboratory has written policies and procedures for modifying blood and blood components.

**Elements of Performance for QSA.05.14.01**
1. The policies and procedures for modification of blood and blood components follow good manufacturing practice and address the following:
   - Maintaining sterility
   - Using US Food and Drug Administration (FDA) approved additives
Pool of multiple blood products
- Thawing procedures
- Storing and processing
- Assigning expiration date and time
- Labeling requirements
- Tracing blood or blood component from source to final disposition
- Documenting reports of unacceptable products and the corrective action and disposition taken
- Varying from established procedures is reviewed and affected products are approved prior to administration

2. The laboratory assigns expiration dates to blood components in compliance with US Food and Drug Administration (FDA) regulation 21 CFR 610.53.

3. The laboratory label affixed to blood or blood components contains all information required by the US Food and Drug Administration (FDA) and is displayed in a format supported by ISBT 128 standards.

Note: If a transfusing facility receives a unit with a Codabar label, the facility may relabel the unit in Codabar format after any manipulation to the product.

4. The laboratory reviews labels for accuracy, adulteration, and legibility after application.

5. The laboratory system allows tracking of blood component numbers from source to final disposition.

6. The laboratory maintains records of the individual donor unit numbers for each unit in a pooled product.

7. All containers, additives, and solutions meet or exceed US Food and Drug Administration (FDA) criteria for collection, preservation, and storage of blood and blood components.

8. If a closed system is not maintained during aliquot preparation of blood components, the expiration date of the product is changed to reflect that of an open system.

95 The AABB Technical Manual is a resource for component preparation procedures.
96 For information on assigning expiration dates to blood components, refer to US Food and Drug Administration (FDA) regulation 21 CFR 610.53.
10. A quality control program is in place to verify that components modified by the laboratory meet US Food and Drug Administration (FDA) requirements for human blood and blood products.

11. The laboratory follows its policies and procedures for modification of blood and blood components.

**Standard QSA.05.14.03**
The laboratory provides plasma products to its patients.

**Elements of Performance for QSA.05.14.03**

1. The laboratory has written policies and procedures that address the processing of plasma components.

2. The laboratory thaws frozen plasma or cryoprecipitate between 30°C and 37°C and protects outlet ports from water contamination.

3. The laboratory stores thawed fresh frozen plasma products between 1°C and 6°C.

4. The laboratory relabels thawed plasma products or byproducts as “thawed plasma.”

5. The laboratory prepares cryoprecipitate according to US Food and Drug Administration (FDA) regulation 21 CFR 640.54.

6. The laboratory stores thawed cryoprecipitate between 20°C and 24°C.

7. The laboratory follows its policies and procedures for modifying plasma products.

8. The laboratory has written policies and procedures that address the transfusion of plasma components containing a significant amount of incompatible ABO antibodies or unexpected red cell antibodies.

**Standard QSA.05.14.05**
The laboratory irradiates blood and blood components according to law and regulation.

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**For information on thawed plasma, refer to US Food and Drug Administration (FDA) regulation 21 CFR 606.122(m).**

**Additional information can be found in the current editions of the AABB’s Standards for Blood Banks and Transfusion Services and Technical Manual.**
Elements of Performance for QSA.05.14.05

The laboratory’s written policies and procedures for irradiation of blood and blood components address the following:

1. ☐ Validation of the target dose of radiation delivered according to the manufacturers’ recommendations and the blood or blood component.

2. ☐ A process to confirm that the target dose of irradiation has occurred.††

3. ☐ Assignment of expiration date not to exceed the original expiration date or 28 days from date of irradiation, whichever is sooner.

4. ☐ Documentation of blood or blood component irradiation, including date and time of irradiation, unit numbers, dose of radiation, duration of radiation, and the staff performing the irradiation.

Standard QSA.05.14.07

The laboratory provides leukoreduced blood and components to its patients.

Elements of Performance for QSA.05.14.07

1. ☐ The laboratory’s written policies and procedures define methods to leukoreduce blood and blood components.

The laboratory’s written policies and procedures to leukoreduce blood and blood components address the following:

2. ☐ Leukocyte reduction to less than 5 x 10^6 for apheresis platelets and red blood cells.

3. ☐ Leukocyte reduction to less than 8.3 x 10^5 for whole blood derived platelets.

4. The laboratory follows its policies and procedures for leukoreduction of blood and blood components.

Standard QSA.05.16.01

The laboratory safeguards the quality and integrity of platelet products it provides to its patients.

†† For additional information, see US Food and Drug Administration guidance, July 22, 1993, “Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products.”
Elements of Performance for QSA.05.16.01

1. The laboratory gently agitates and maintains platelet components at temperatures between 20°C and 24°C.

2. The laboratory has a system in place to limit and detect, or inactivate bacteria in platelet components.

Standard QSA.05.17.01
The laboratory has policies and procedures for transfusion-related activities.

Elements of Performance for QSA.05.17.01

1. The laboratory has written policies and procedures for transfusion-related activities. 

2. Policies and procedures for transfusion-related activities address the following:
   - Positive identification of the blood recipient and the blood container, including matching the recipient information to the blood or blood component being transfused
   - Use of filters, warming devices, and cell salvage processes, including the transfusion service director’s responsibilities for these activities
   - Special or urgent situations (for example, life-threatening emergencies)

Note: Additional practice guidance on transfusion-related activities can be found in current AABB standards.

3. The laboratory has distinct written policies and procedures for neonatal transfusion-related activities.

4. The laboratory follows its policies and procedures for transfusion-related activities.

Standard QSA.05.18.01
The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events.

Additional information can be found in the current editions of the AABB’s Standards for Blood Banks and Transfusion Services and Technical Manual.
Elements of Performance for QSA.05.18.01

1. The organization has written policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration. 

2. Policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration address the following:
   - The protocol for monitoring patients during blood and blood component administration
   - The criteria for recognizing a suspected transfusion-related adverse event
   - The protocol to follow if a suspected transfusion-related adverse event occurs
   - The requirement that suspected transfusion-related adverse events are reported immediately to the physician responsible for the patient
   - The requirement that suspected transfusion-related adverse events are reported immediately to the laboratory, whether or not the physician responsible for the patient deems it necessary to report the event

3. Policies and procedures for nursing services related to blood and blood component administration do not conflict with the laboratory’s policies and procedures.

4. Patient care staff monitor the patient during blood and blood component administration to detect suspected transfusion-related adverse events. The monitoring is documented.

5. The organization provides training for staff who administer and monitor blood and blood component transfusions. The training is documented.

6. The organization assesses competency for staff who administer and monitor blood and blood component transfusions. The competency is documented.

7. The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration.

Standard QSA.05.19.01

The laboratory has policies and procedures for reporting and investigating suspected transfusion-related adverse events.
Elements of Performance for QSA.05.19.01

1. 🟩 The laboratory has written policies and procedures for investigating suspected transfusion-related adverse events. R

2. Policies and procedures for investigating suspected transfusion-related adverse events address the following: R
   - Laboratory responsibility for investigation
   - The transfusion service director’s review and interpretation
   - Record maintenance
   - Nursing responsibility for monitoring and reporting events to the laboratory
   - Nursing responsibility for monitoring and reporting events to a physician responsible for the patient

3. The written policies and procedures for investigating suspected transfusion-related adverse events are readily accessible to nursing staff. R

4. The laboratory follows its policies and procedures for investigating suspected transfusion-related adverse events. R

Standard QSA.05.19.03
The laboratory investigates the cause of suspected transfusion-related adverse events immediately upon notification.

Elements of Performance for QSA.05.19.03

1. 🟩 The laboratory has written policies and procedures for investigating a suspected transfusion-related adverse event, including the protocol for a transfusion reaction workup. R

2. 🟩 The transfusion reaction workup protocol includes written criteria to determine if a hemolytic reaction has occurred. R

3. The laboratory evaluates the suspected transfusion-related adverse event immediately upon notification and to the extent determined by the transfusion service director. R

4. When a transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory reviews all policies and procedures to prevent recurrence and provide for the safety of individuals being transfused. R

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**Refer to AABB Standards, Section 7.4, and the AABB Technical Manual for reaction categories.**
5. When a suspected transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory takes corrective action to prevent recurrence. The corrective action is documented. 

6. The laboratory reports all confirmed fatal transfusion reactions to the US Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research (CBER). (Refer to the “Sentinel Events” [SE] chapter.) 

7. Per federal regulation, the laboratory notifies the US Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research when a biological product deviation occurs. 

**Standard QSA.05.19.05**
The transfusion service director interprets each suspected transfusion-related adverse event.

**Elements of Performance for QSA.05.19.05**

1. The transfusion service director interprets the evaluation of test results provided as part of the transfusion reaction workup. The interpretation is documented. 

2. The interpretation of the transfusion reaction workup provided by the transfusion service director is documented in the patient’s clinical record. 

**Standard QSA.05.20.01**
If blood or blood components have been administered that are potentially infected with human immunodeficiency virus (HIV), the laboratory identifies recipients and informs them of the risk of infection.

**Elements of Performance for QSA.05.20.01**

1. Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for human immunodeficiency virus (HIV).

2. The laboratory has written procedures for the notification of blood recipients of potential human immunodeficiency virus (HIV) infection.

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For information on how and when to report information to the FDA, see http://www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/transfusiodonationfatalities/default.htm.
3. The laboratory’s human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient’s attending licensed independent practitioner (physician of record) of the recipient’s potential for HIV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HIV testing and counseling.

4. The laboratory’s human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person, of the potential for HIV infection and to inform him or her of the need for HIV testing and counseling, if the physician is unavailable or declines to notify the recipient.

5. The laboratory’s human immunodeficiency virus (HIV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HIV infection, including whether the recipient was located.

**Note:** Documentation of notification attempts are in accordance with federal guidelines.

6. The laboratory’s human immunodeficiency virus (HIV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability.

7. The laboratory follows its procedures for notification of blood recipients of potential human immunodeficiency virus (HIV) infection.

**Standard QSA.05.21.01**

If blood or blood components have been administered that are potentially infected with hepatitis C (HCV), the laboratory identifies recipients and informs them of the risk of infection.

**Elements of Performance for QSA.05.21.01**

1. Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for hepatitis C (HCV).

2. The laboratory has written procedures for the notification of blood recipients of potential hepatitis C (HCV) infection.
3. The laboratory’s hepatitis C (HCV) procedures require the transfusing facility to make several attempts to contact the blood recipient’s attending licensed independent practitioner (physician of record) of the recipient’s potential for HCV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HCV testing and counseling.

4. The laboratory’s hepatitis C (HCV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person of the potential for HCV infection and inform him or her of the need for HCV testing and counseling, if the physician is unavailable or declines to notify the recipient.

5. The laboratory’s hepatitis C (HCV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HCV infection, including whether the recipient was located.

6. The laboratory’s hepatitis C (HCV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability.

7. The laboratory follows its procedures for notification of blood recipients of potential hepatitis C (HCV) infection.

**Standard QSA.05.22.01**

The laboratory retains records on the receipt, testing, and disposition of blood and blood components.

**Elements of Performance for QSA.05.22.01**

1. The laboratory retains an audit trail detailing the receipt and disposition of all blood and blood components for 10 years.

2. The documentation of testing of blood and blood components is retained for at least five years.

3. For blood and blood components issued by the facility that collected and processed the unit, the identification of the recipient is retained for 10 years.

**Standard QSA.05.23.01**

The laboratory has written policies and procedures related to blood donation.
Elements of Performance for QSA.05.23.01

1. The laboratory’s written policies and procedures for blood donation are consistent with US Food and Drug Administration (FDA) regulations.

2. The policies and procedures for blood donation meet criteria for donor screening as defined by the US Food and Drug Administration (FDA) regulations.

3. The policies and procedures for blood donation address phlebotomy and testing.

4. The policies and procedures for blood donation address quality control testing and maintenance of equipment and supplies.

5. The laboratory performs a history and physical examination of the blood donor.

6. The laboratory makes emergency medical care available at all times while blood is being drawn from donors.

7. The laboratory calibrates equipment used to regulate blood volume collected from blood donors and individuals undergoing therapeutic phlebotomy against a known mass or volume before initial use, on day of donor or patient phlebotomy, and following maintenance or repairs for accuracy.

8. The laboratory retains—for an indefinite period of time—the testing records for blood donors who are permanently deferred.

9. The laboratory follows its policies and procedures for blood donation.

Standard QSA.05.24.01

The laboratory communicates with the blood donor regarding the donation process and risks.

Elements of Performance for QSA.05.24.01

1. The laboratory protects the confidentiality of the donor’s information throughout the donation event, including post-donation information sharing.

2. Prior to blood donation, the laboratory provides educational material to the donor explaining the process of infectious disease transmission by blood transfusion and the signs and symptoms of Acquired Immune Deficiency Syndrome (AIDS).

*** The current CFR and blood guidance from the US Food and Drug Administration (FDA) can be found at http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm.
3. The donor acknowledges understanding of educational materials provided.

4. Donor consent for procedure is obtained prior to blood donation.

5. The laboratory has processes to notify the donor of any clinically significant abnormal findings as defined by the US Food and Drug Administration (FDA) and the medical director.

**Standard QSA.05.24.03**

The laboratory safely collects, stores, handles, processes, tests, and labels blood or blood components.

**Elements of Performance for QSA.05.24.03**

1. The laboratory has written policies and procedures that address blood donor collection, including handling, processing, testing, dating, labeling, storing, and distributing, according to state and federal regulation.

2. The policies and procedures for blood donor collection address the making of blood components.

3. The laboratory tests a sample from each blood donation for ABO, Rh typing, and antibody screening.

4. The laboratory tests a sample from each blood donation for infectious agents as specified by the US Food and Drug Administration (FDA).

5. The laboratory does not use blood or blood components that test reactive for an infectious agent unless allowed by US Food and Drug Administration (FDA).

6. The laboratory complies with US Food and Drug Administration (FDA) specifications for donor blood labels.

**Note:** *ISBT 128 is the preferred bar code symbology and should be used in accordance with International Council for Communality in Blood Banking Automation (ICCBBA) standards, whenever possible.*

7. The laboratory follows bacterial contamination prevention procedures in the collection, storage, handling, processing, and testing of blood and blood components.

Additional practice guidance may be found in the AABB standards or AABB Technical Manual.

8. The laboratory establishes procedures to prevent inadvertent release of unsuitable units (for example, an organized grouping of components and blood in temperature-controlled places and the use of computer alerts).

**Standard QSA.05.25.01**
The laboratory, or designated department, monitors therapeutic phlebotomy, plasma-apheresis, and apheresis procedures.

**Rationale for QSA.05.25.01**
The samples of each transfused unit and recipient blood are retained for further testing in the event of an adverse reaction.

**Elements of Performance for QSA.05.25.01**

1. The laboratory’s or designated department’s written policies and procedures for therapeutic apheresis address:
   - Documentation of doctor’s orders
   - Patient informed consent process
   - Acceptance of medical responsibility for the procedure
   - Treatment of adverse reactions
   - Patient monitoring
   - Documentation of procedure

2. The laboratory or the designated department documents the following elements in the patient’s therapeutic apheresis record:
   - Patient identification
   - Diagnosis
   - Equipment serial number
   - Operator
   - Date and time of procedure start and end
   - Lot numbers of all fluids used and replaced in the device
   - Blood volume processed
   - Amount of fluid removed from patient
   - Patient assessment
   - Time out procedure prior to placing venous access device

**Note:** Equipment serial numbers are not required for therapeutic phlebotomy performed by gravity.
3. The laboratory or designated department uses equipment and fluids approved by the US Food and Drug Administration (FDA) for apheresis procedures. Manufacturers’ instructions are followed.

4. Blood collected from therapeutic phlebotomy is not used for transfusion unless specifically approved by the US Food and Drug Administration (FDA).

5. A qualified physician accepts medical responsibility for all therapeutic blood collection and exchange procedures, including those performed perioperatively.

6. Therapeutic apheresis procedures are ordered by the patient’s physician with instructions regarding frequency, volume, and number of procedures to perform.

8. Staff follow the laboratory’s or designated department’s policies and procedures for apheresis.

**Standard QSA.06.01.01**

The laboratory verifies each clinical chemistry test system through the use of quality control materials.

**Element of Performance for QSA.06.01.01**

1. The laboratory performs at least one level of quality control material with each clinical chemistry run of patient specimens. The quality control results for each run are documented.

   **Note:** The laboratory defines a “run” for each test system. Within each 24-hour period, the laboratory tests each level of quality control material at least once.

**Standard QSA.06.02.01**

The laboratory verifies the operation of each blood gas testing instrument through the use of quality control materials.

**Elements of Performance for QSA.06.02.01**

1. The laboratory tests at least two different levels of quality control materials for blood gas testing each day the procedure is performed. The combination of controls and calibrators used each day of testing are rotated to check normal, alkalosis, and acidosis levels. The quality control results are documented.

2. The laboratory tests at least one level of quality control material for each eight hours of patient blood gas testing. The quality control results are documented.
Note: The laboratory should attempt to perform quality control testing as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before or after the 8-hour mark, providing a 30-minute window. Ranges in excess of +/- 30 minutes that produce a window of more than an hour do not meet the intent of this element of performance.

3. The laboratory tests at least one level of quality control material each time patients are tested unless automated instrumentation verifies calibration internally every 30 minutes.

Standard QSA.06.03.01
The laboratory’s procedures for maternal serum marker prenatal screening provide for accurate results.

Elements of Performance for QSA.06.03.01
The laboratory’s written quality control and testing procedures for maternal serum marker prenatal screening include the following:

1. Establishment of laboratory specific median values or verification of manufacturer’s median values consistent with the population served.
2. Criteria and frequency for recalculation or reverification of the median values at specifically defined intervals.
3. Evaluation of new reagent lots against the current median values with adjustments of the median in response to changes in median values that affect clinical interpretation.
4. The laboratory follows its quality control and testing procedures for maternal serum marker prenatal screening.

Standard QSA.06.03.03
The laboratory procedures for maternal amniotic fluid alpha fetal protein (AFAFP) provide for accurate results.

Elements of Performance for QSA.06.03.03
1. The laboratory has written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP).

The laboratory’s written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following:
2. Establishment of laboratory-specific median values or verification of a manufacturer’s median values consistent with the population served.

3. Criteria and frequency for recalculation or reverification of the median values at specific intervals.

4. Inclusion of a minimum of one amniotic fluid dilution control with each run.

5. Determination of presence or absence of fetal blood contamination in fluids visibly contaminated with blood.

6. Criteria for confirmatory testing requirements for abnormal amniotic alpha fetal protein results.

7. The laboratory follows its quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP).

**Standard QSA.06.04.01**
The laboratory’s procedures for high performance liquid chromatography (HPLC) provide for accurate results.

**Elements of Performance for QSA.06.04.01**
The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following:

1. The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.

2. Extraction and use of control materials that challenge each step of the testing process.

3. For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis.

4. The detection and evaluation of carryover.

5. The frequency of monitoring column and detector performance.

6. The laboratory follows its procedures for high performance liquid chromatography (HPLC).

**Standard QSA.06.04.03**
The laboratory’s procedures for gas chromatography (GC) provide for accurate results.
Elements of Performance for QSA.06.04.03

The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following:

1. The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.
2. Extraction and use of control materials that challenge each step of the testing process.
3. For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis.
4. The detection and evaluation of carryover.
5. For quantitative tests, an established reportable range and limit of detection.
6. The laboratory follows its procedures for gas chromatography (GC).

Standard QSA.06.04.05

The laboratory’s procedures for mass spectrometry provide for accurate results.

Elements of Performance for QSA.06.04.05

The laboratory has written quality control and testing procedures for mass spectrometry that address the following:

1. The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.
2. Extraction and use of control materials that challenge each step of the testing process.
3. Criteria and frequency for establishing mass calibration and optimum performance.

Note: Some organizations refer to mass spectrometer optimum performance as being “in tune.” Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).

4. The detection and evaluation of carryover.
5. (i) For quantitative tests, an established reportable range and limit of detection.

6. (i) Establishment and validation of identification criteria for the specific technique applied (for example, liquid chromatography–mass spectrometry versus gas chromatography–mass spectrometry).

**Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) documents C62 (Liquid Chromatography–Mass Spectrometry Methods) and C43 (Gas Chromatography–Mass Spectrometry Confirmation of Drugs).

7. (i) Liquid chromatography–mass spectrometry includes evaluation, reduction, and monitoring of matrix effects and ion suppression.

**Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).

8. The laboratory follows its procedures for mass spectrometry.

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**Standard QSA.07.01.01**

The laboratory follows an approved clinical guideline† when performing urine tests on specimens that meet acceptability criteria.

**Rationale for QSA.07.01.01**

Unless a urine specimen is fresh or properly preserved, it will not yield accurate results. This applies to most of its analyzed constituents, including the microscopic examination.

**Elements of Performance for QSA.07.01.01**

1. The laboratory performs urine tests only on fresh or preserved specimens.

2. The laboratory establishes and follows a defined system for handling, testing, and reporting urine specimens that exceed stability requirements (for example, room temperature urine more than two hours old and refrigerated urine more than four hours old).

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† Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document GP16 (Urinalysis).
Standard QSA.07.02.01
The laboratory makes reference materials available for microscopic examination of urine sediment.

Element of Performance for QSA.07.02.01
1. For microscopic examination of urine sediment, the laboratory makes reference materials available to help with identification.

Standard QSA.08.01.01
The laboratory director or the cytology technical supervisor determines qualifications and number of cytology staff.

Elements of Performance for QSA.08.01.01
1. The laboratory director or cytology technical supervisor determines cytology staff qualifications.¹
2. The laboratory complies with federal and state personnel qualification and licensure requirements.²
3. The laboratory director or cytology technical supervisor provides a number of cytotechnologists sufficient to review the volume and variety of cytology cases.

Standard QSA.08.02.01
The cytology technical supervisor establishes policies and procedures for the testing of cytology specimens.

Elements of Performance for QSA.08.02.01
1. The cytology technical supervisor establishes written policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.
2. Policies and procedures for cytology specimen collection include the criteria for unacceptable cytology specimens.

**Note 1:** The following list of common criteria may be used to define an unacceptable cytology specimen:

- The name on the slide or specimen container is different from the name on the requisition.
- The slide or container is not labeled according to the laboratory’s procedure regarding specimen collection.
- The submitted slide is broken or crushed and cannot be repaired for processing.
- The specimen is improperly fixed.

**Note 2:** For more information on specimen collection procedures, please refer to the “Document and Process Control” (DC) chapter, Standard DC.01.01.01.

3. Policies and procedures for cytology specimen evaluation include the criteria for unsatisfactory specimens that do not allow for a definitive diagnosis.

**Note:** The following list of common criteria may be used to define an unsatisfactory cytology specimen. Slides containing or showing signs of:

- Too few cells
- Obscuring of cells
- Obscuring inflammation
- Obscuring red blood cells
- Obscuring lubricant
- Excessive air drying
- Excessive cellular degeneration

4. The laboratory communicates the policies and procedures for cytology specimen collection, identification, preservation, and transport to clinical staff and other clients who collect cytology specimens.

5. The laboratory rejects unacceptable cytology specimens.

6. The laboratory notifies the sender when unacceptable cytology specimens are received.

7. The laboratory follows its policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.

**Standard QSA.08.03.01**

The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.
Elements of Performance for QSA.08.03.01

1. The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services.

2. The quality improvement plan includes a system to detect errors in the cytologic examination process and a process to report results.

3. The laboratory reviews all gynecologic and nongynecologic cytology reports with available patient clinical information and compares the results of the review for discrepancies.

4. The laboratory reviews all gynecologic cytology reports of a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology reports and compares the results of the review for discrepancies.

5. For all gynecologic slides with current high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm, the laboratory reviews all normal or negative gynecologic specimens received within the previous five years, if available to the laboratory (on site or in storage), documents discrepancies, and issues a corrected report for any discrepancies that would affect patient care.

6. The laboratory determines the causes of any cytology discrepancies when comparing the following:
   - Gynecologic and nongynecologic reports with available patient clinical information
   - Gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report
   - A current HSIL, adenocarcinoma, or other malignant neoplasm with previous (normal or negative) gynecologic specimens from the previous five years

7. The laboratory performs reeducation and other corrective actions (for example, adjusting workload, if indicated) for significant cytology discrepancies as defined by the cytology technical supervisor. Reeducation and other corrective actions occur within a time frame that prevents recurrence. The performance is documented.

8. The laboratory annually generates an aggregated statistical report that includes the following:
   - The number of cytology cases examined
The number of specimens processed by specimen type
The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation)
The number of gynecologic cases with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which the histology results were available for comparison
The number of gynecologic cases in which cytology and available histology reports are discrepant
The number of gynecologic cases in which a rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm(s)

9. The laboratory assesses communications with the clinical staff and makes improvements so that the following can be maintained at an acceptable level:
   - Collection and identification of specimens
   - Completion of the cytology requisition with the required information, such as date of birth, date of the last menstrual period, previous abnormal findings for Pap tests, and other abnormal findings from previous Pap tests or other specimens
   - Follow-up on abnormal findings with clinical consultation, when indicated
   - Notification of the patient’s physician and issuance of an amended report for significant cytology discrepancies that affect patient care

10. The laboratory measures, assesses, and improves the quality of cytology services.

**Standard QSA.08.04.01**
The laboratory establishes workload limits for staff who perform primary cytology screening.

**Elements of Performance for QSA.08.04.01**

1. The laboratory has written policies and procedures that address cytology workload limits.

2. The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening.

3. The cytology workload limit is based on each staff member’s performance using evaluations of the following:
Review of 10% of the cases interpreted as negative (See also QSA.08.06.01, EP 2)

Comparison of the primary screener’s initial cytologic interpretation with the pathologist’s final interpretation (See also QSA.08.07.01, EP 2)

Other measures as established by the cytology technical supervisor

**Note 1:** Staff members include individuals who perform primary screening and individuals who perform quality control re-examinations.

**Note 2:** Individuals that qualify under CFR §493.1449(k) are not required to perform the 10% rescreen of negative cases on their own cases. This requirement applies exclusively to the cytology general supervisor and cytotechnologist.

4. Workload requirements apply to all cytotechnologists, pathologists, and pathology residents in the final year of training leading to board certification.

5. For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is 100 slides (or full slide equivalents) per 24-hour period for either gynecologic or nongynecologic specimens or both. For gynecologic specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer as approved by the US Food and Drug Administration (FDA).

**Note 1:** For manual screening, liquid-based gynecologic preparations cannot be counted as a half slide. All gynecologic slide preparations (liquid-based or conventional) are counted as one full slide.

**Note 2:** The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload. When performing evaluations using automated and semiautomated screening devices, the laboratory conforms to current manufacturer’s instructions.

**Note 3:** Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide.
Note 4: The 100-slide limit includes previously unevaluated gynecologic slides and nongynecologic slides, 10% rescreen slides, and review slides. Cytology technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100-slide workload limit.

Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecologic cases; previously examined nongynecologic cytology preparations; or tissue pathology slides examined by a cytology technical supervisor.

6. The maximum number of cytology slides is examined in no less than an eight-hour workday.

Note 1: For the purposes of establishing workload limits for staff examining slides by nonautomated microscopic technique on other than an eight-hour workday basis (including full-time employees with duties other than slide examination and part-time employees), a period of eight hours must be used to prorate the number of slides that may be examined. Use the following formula: (number of hours examining slides x 100) ÷ 8 = maximum slide volume to be examined.

Note 2: For both nonautomated microscopic techniques and automated/semiautomated microscopic techniques, laboratories must consider the time spent reading each slide to achieve consistent quality results without exceeding the maximum workload requirements. For information on how laboratorians can safely calculate workload for semi-automated gynecologic cytology screening devices approved by the US Food and Drug Administration (FDA), refer to http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm.

7. Both the laboratory and the cytotechnologist maintain workload records of the total number of cytology slides examined, regardless of the site or laboratory, and the number of hours spent examining slides for each 24-hour period.

8. The cytology technical supervisor reassesses the workload limits for each staff member every six months, or more frequently as specified in the laboratory’s policy. The reassessment is documented.

9. The cytology technical supervisor reestablishes, in writing, workload limits for each staff member through a documented assessment of case reviews based on each staff member’s performance against the laboratory’s overall statistical values.
10. The cytology technical supervisor investigates any discrepancies with the assessment of staff performance, including reasons for deviation and any corrective actions taken. The investigation is documented.

11. The cytology technical supervisor makes adjustments in each staff member’s workload, if needed, based on the results of the workload assessment.

12. The laboratory follows its policies and procedures for cytology workload limits.

**Standard QSA.08.05.01**

Cytology slide staining provides acceptable quality.

**Elements of Performance for QSA.08.05.01**

1. The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation.

2. All gynecologic specimens are stained using a Papanicolaou or modified Papanicolaou staining method.

3. The laboratory takes measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the cytology staining process.

4. The laboratory separately stains nongynecologic specimens that have a high potential for cross-contamination from other nongynecologic specimens.

5. The laboratory filters or changes the cytology stains following the staining of nongynecologic specimens with a high potential for cross-contamination.

**Standard QSA.08.06.01**

The cytology quality system includes review of a random sample of negative gynecologic slides.

**Elements of Performance for QSA.08.06.01**

1. A qualified individual reviews a random sample of negative gynecologic slides before reporting patient results. The review is documented.

2. The review of a minimum of 10% of negative gynecologic slides includes the following:

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A random sample of 10% of all gynecologic cases read by each primary screener and interpreted to be negative for epithelial cell abnormalities and malignant or premalignant conditions

Patients identified as having a higher-than-average probability for developing cervical cancer

Slides from each primary screener

(See also QSA.08.04.01, EP 3)

Note 1: During the initial screening process, primary screeners are not made aware of which slides will be reexamined.

Note 2: The 10% review of negative cases is not required for a one-person laboratory consisting of a cytology technical supervisor or for a laboratory that only employs pathologists qualified as cytology technical supervisors. However, all laboratories must establish and follow a program to detect errors.

3. A qualified individual completes the review of a random sample of negative gynecologic slides before reporting patient results.

4. Records of the review of a random sample of negative gynecologic slides are available and include initial examinations and rescreening results. The results are documented.

Standard QSA.08.06.03

The cytology laboratory has a process to correlate cytologic interpretations with the corresponding histologic finding.

Elements of Performance for QSA.08.06.03

1. The laboratory has written policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings.

2. The laboratory follows its policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings. The discrepancies and their resolutions are documented.

Standard QSA.08.07.01

The cytology technical supervisor reviews cytology slides.
Elements of Performance for QSA.08.07.01

1. □ An individual qualified as a cytology technical supervisor reviews and confirms all nongynecologic slides. This review is documented. 

2. □ A cytology technical supervisor reviews and confirms all gynecologic slides interpreted as reactive or reparative, premalignant or malignant, or any of the following epithelial cell abnormalities: 
   - Squamous cell
   - Atypical squamous cells of undetermined significance (ASC-US) or high-grade squamous intraepithelial lesion (HSIL) (ASC-H)
   - LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1)
   - HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion
   - Squamous cell carcinoma
   - Glandular cell
   - Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, glandular)
   - Atypical cells favor neoplastic (endocervical or glandular)
   - Endocervical adenocarcinoma in situ
   - Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS
   - Other malignant neoplasms

   This review is documented. (See also QSA.08.04.01, EP 3)

3. □ All gynecologic and nongynecologic test reports reviewed by a cytology technical supervisor have a written or secured electronic signature.

Standard QSA.08.08.01

Cytology reporting includes processes to communicate with the authorized person ordering the test and, if different, the individual responsible for using the test results.

Elements of Performance for QSA.08.08.01

1. □ For all specimen results, cytology reports contain descriptive nomenclature that facilitates communication between the laboratory and the clinician.

2. The cytology laboratory communicates results that require urgent patient follow-up to the authorized person ordering the test and, if different, the individual responsible for using the test results. The communication is documented.

3. Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

4. Diagnostic interpretations are not reported on unsatisfactory specimens.

5. When an incorrect cytology result is reported, a corrected report is generated and indicates the basis for the correction. (See also QSA.02.12.01, EP 9)

6. When an incorrect cytology result is reported, the laboratory communicates directly with the ordering physician or other authorized individual qualified to follow up with the patient. The communication is documented. (See also QSA.02.12.01, EP 9)

7. When a gynecologic cytology examination method is automated, the cytology report includes the automated instrument used.

Standard QSA.08.09.01
Cytology slides are maintained, stored, and retrieved.

Elements of Performance for QSA.08.09.01

1. The laboratory maintains and stores cytology slide preparations under conditions that allow preservation.

2. The laboratory retains cytology slide preparations for at least five years from the examination date, or longer as required by state law or regulation.

3. The laboratory retrieves cytology slide preparations on request.

4. The laboratory maintains documentation for cytology slides loaned or referred for purposes other than proficiency testing.

Note: Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of these slides.
Standard QSA.09.01.01
The laboratory establishes written policies and procedures for processing cytogenetic samples.

Element of Performance for QSA.09.01.01
1. The laboratory has written policies and procedures for processing cytogenetic specimens that address the following:
   - The use of separate incubators equipped with independent electrical circuits or emergency power systems and emergency alarms for amniotic fluid and chorionic villus cultures
   - Duplicate or independently established cultures for each tissue type whenever possible
   - Independent harvesting of duplicate amniotic fluid and chorionic villus flasks or plates

Standard QSA.09.02.01
The laboratory maintains individual sample identification during all phases of cytogenetic testing and reporting.

Elements of Performance for QSA.09.02.01
1. The laboratory has written policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting.

The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following:

2. Specimen collection and accessioning.
3. Cultures.
5. Photography or another image reproduction technique.
6. Photographic printing and storage.
7. Karyotypes and photographs.
8. The laboratory follows its policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting.
Standard **QSA.09.03.01**

The cytogenetic laboratory has written quality control and testing procedures for conventional chromosomal analyses studies.

**Elements of Performance for QSA.09.03.01**

1. The cytogenetic laboratory procedures for conventional chromosomal analyses studies provide reliable results.

The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following:

2. Determination of the number of cells to count and/or analyze and the number karyotyped based on tissue type, culture method, and clinical reason for referral as follows:

   **Cells to count**
   - For peripheral blood samples (non-neoplastic disorders), a minimum of 20 cells
   - For amniotic fluid (in situ) samples, a minimum of 15 cells from a minimum of 15 colonies
   - For non-amniotic fluid cell cultures, a minimum of 20 cells
   - For chorionic villus cultured preparation samples, a minimum of 20 cells
   - For solid tissue samples, a minimum of 20 cells

   **Note:** *When mosaicism is suspected, a minimum of 30 cells*
   - For amniotic fluid (in situ) samples, a minimum of 15 cells from a minimum of 15 colonies
   - For non-amniotic fluid cell cultures, a minimum of 20 cells
   - For chorionic villus cultured preparation samples, a minimum of 20 cells
   - For solid tissue samples, a minimum of 20 cells

   **Cells to analyze**
   - Minimum of five cells for the following samples: amniotic fluid (in situ), cultured chorionic villus, non-neoplastic blood cells, and non-neoplastic solid tissue
   - Minimum of 20 cells, whenever possible, for neoplastic studies of marrow, blood, or solid tumor specimens
   - Two or more cultures, whenever possible, for neoplastic bone marrow, blood, or solid tumor specimens

   **Cells to karyotype**
   - Two cells karyotyped for each non-neoplastic case study, with at least one karyogram per cell line for amniotic fluid, chorionic villus, solid tissue, and peripheral blood cell specimens
For neoplastic case studies, a minimum of two cells karyotyped, and in addition, one karyogram for each subclone, and one karyogram of a normal cell if observed for solid tumor, blood, or bone marrow specimens

3. □ Determination of X and Y chromatin counts based on the performance of a full chromosome analysis.

4. □ Level of band resolution necessary for interpretation purposes.

5. □ Confirmatory testing performed for atypical results.

6. □ Criteria for clinical circumstances in which an abbreviated chromosome study may be conducted.

7. The laboratory follows its quality control and testing procedures for cytogenetics.

**Standard QSA.09.03.03**
The laboratory’s cytogenetic breakage studies include quality controls.

**Element of Performance for QSA.09.03.03**

1. Both a negative (normal) and a positive control are included in each culture event whenever breakage studies are performed for diagnosis.

**Standard QSA.09.03.05**
The laboratory’s procedures for fluorescence in situ hybridization (FISH) provide for accurate results.

**Elements of Performance for QSA.09.03.05**
The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following:

1. □ Validation of each probe.

2. □ Establishment of normal cut off values for each probe.

3. □ Use of a control consistent with hybridization assay based on signal patterns of hybridization and specimen type.

4. The laboratory uses internal or external control loci for each fluorescence in situ hybridization (FISH) test. The use of control loci is documented.
The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following:

5. Criteria for scoring results.

6. The laboratory follows its written policies and procedures for fluorescence in situ hybridization (FISH) testing.

**Standard QSA.09.03.07**

The laboratory’s chromosomal microarray analysis provides accurate results.

**Elements of Performance for QSA.09.03.07**

1. The laboratory has written quality control and testing procedures for chromosomal microarray analysis.

2. The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: probe specificity.

3. The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: assessment of the genomic copy number.

4. The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: assay resolution.

5. The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: study limitations, including copy number variation.

6. The laboratory follows its written quality control and testing procedures for chromosomal microarray analysis.

**Standard QSA.09.04.01**

The laboratory documents the stages of the cytogenetic testing process and the results.

**Elements of Performance for QSA.09.04.01**

The laboratory documents the stages of the cytogenetic testing process and results, including the following:

1. The media used.

2. The reactions observed.
3. The number of cells counted.
4. The number of cells karyotyped.
5. The number of chromosomes counted for each metaphase spread.
6. The quality of the banding.
7. The resolution, based on the clinical information provided to the laboratory for the type of tissue or specimen and the type of study required.
8. An adequate number of karyotypes prepared for each patient.
9. The culture conditions.
10. The incubation times.

**Standard QSA.09.05.01**
The laboratory’s cytogenetic interpretive reports include specific testing information.

**Elements of Performance for QSA.09.05.01**
The laboratory interpretive reports for cytogenetic testing include the following information:

1. A summary and interpretation of the observations.
2. The number of cells counted and analyzed.
4. Documentation of any preliminary report, such as a verbal or telephone report.
5. All clinical information required for interpretation.
6. Band resolution for constitutional cases.

**Standard QSA.09.06.01**
The laboratory retains materials of cytogenetic case studies.

**Elements of Performance for QSA.09.06.01**
1. The laboratory retains materials of processed cytogenetic case studies for at least the following periods:
Original specimens and cultures: until metaphase cells are provided for analysis
- Cell pellets: 2 weeks after final report is issued
- Permanently stained slides: 3 years
- Negatives, prints, digitized images: 20 years
- Final reports: 20 years

2. The laboratory permanently retains slides, negatives, prints, or magnetic media of abnormal cases identified by cytogenetic testing.

**Standard QSA.09.07.01**
The cytogenetic laboratory reports results within a defined time frame.

**Elements of Performance for QSA.09.07.01**

1. The preliminary report (verbal or written) for stat chromosome analyses is provided within three calendar days from receipt of sample in at least 90% of cases.

2. The final report of stat chromosome analyses is provided within seven calendar days from receipt of sample in at least 90% of cases.

3. The final report of amniotic fluid and chorionic villi analyses is provided within 14 calendar days from receipt of sample in at least 90% of cases.

4. The final report of routine peripheral blood analyses is provided within 28 calendar days from receipt of specimen in at least 90% of cases.

5. The final report of neoplastic blood and bone marrow analyses is provided within 21 calendar days from receipt of specimen in at least 90% of cases.

6. The final report of non-neoplastic blood and bone marrow analyses is provided within 21 calendar days from receipt of sample in at least 90% of cases.

**Standard QSA.09.07.03**
The cytogenetic laboratory collects data to monitor its performance.

**Elements of Performance for QSA.09.07.03**

1. The cytogenetic laboratory maintains a record of report turnaround time statistics for the following chromosomal analyses and specimen types: (For more information, refer to standard PI.03.01.01)
   - Preliminary report for stat chromosomal analyses
- Final report of stat chromosomal analyses
- Final report of amniotic fluid and chorionic villi analyses
- Final report of routine peripheral blood analyses
- Final report of non-neoplastic blood and bone marrow analyses

2. The cytogenetic laboratory maintains a record of culture failure rates for chromosomal analyses including:
   - Amniotic fluid
   - Chorionic villi

   (For more information, refer to PI.03.01.01)

3. The cytogenetic laboratory collects data related to fluorescence in situ hybridization (FISH) performance including:
   - Monitors of hybridization efficiency
   - Monitors of probe signal intensity

   (For more information, refer to PI.03.01.01)

**Standard QSA.10.01.01**

Embryo laboratory procedures provide for accurate results.

**Note:** Embryos are examples of a tissue. For more information on tissue storage and issuance, see the “Transplant Safety” (TS) chapter.

**Elements of Performance for QSA.10.01.01**

1. The embryo laboratory has written procedures for each laboratory test performed.

2. The embryo laboratory’s procedures address the following:
   - Infectious disease assessments
   - Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
   - Insemination schedule relative to oocyte maturity
   - Volume, numbers, and quality of sperm used for insemination of each oocyte
   - Disposition of oocytes with an abnormal number of pronuclei
   - Disposition of excess oocytes
   - The time period following insemination for examination of oocytes to determine fertilization
   - Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
Cryopreservation of specimens

- Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check

- Confirmation of patient identity and the identification of gametes and embryo samples

- Obtaining informed consent

3. The embryo laboratory maintains a system that provides for patient identification and preparation; specimen collection, identification, and handling (transportation, processing, storage, preservation); and accurate recording and reporting of laboratory procedural outcomes.

4. The embryo laboratory follows its procedures for each laboratory test it performs.

**Standard QSA.10.02.01**
The embryo laboratory has a process for method validation.

**Elements of Performance for QSA.10.02.01**

1. The embryo laboratory has written procedures for method validation.

2. The embryo laboratory determines performance measures and demonstrates that the procedures meet or exceed acceptable levels of performance.

3. The embryo laboratory verifies through its performance improvement activities each procedure’s continued acceptable level of performance.

4. The embryo laboratory validates all assisted reproductive technology procedures selected or established by the embryo laboratory before routine patient use.

**Standard QSA.10.03.01**
The embryo laboratory maintains records during all phases of testing and reporting.

**Rationale for QSA.10.03.01**
A well-designed record system helps ensure reliable identification and control of the patient’s specimens as they are received and the laboratory procedures are performed.
Elements of Performance for QSA.10.03.01

1. The embryo laboratory maintains records and dates of laboratory testing and reporting.

2. The embryo laboratory records include the following:
   - Each patient’s assisted reproductive technology cycle
   - Semen assessment before and after processing and concentration for insemination
   - Outcome of insemination or micromanipulation procedures (for example, fertilization)
   - Outcome of any culture (for example, cleavage)
   - Relative timing of protocol events (for example, incubation hours)
   - Assessment of the developmental status and quality of all embryos at transfer
   - Verification that no embryos remain in the catheter following completion of transfer
   - The identity and lot numbers of media and media supplements used in each phase of the procedure
   - The identity of the laboratory staff who handled the specimens and performed the procedures

Standard QSA.10.04.01

The embryo laboratory documents quality control methods for the media it uses.

Element of Performance for QSA.10.04.01

1. The embryo laboratory documents the following for the media it uses:
   - Procedures for the quality control of culture media
   - Completion of a visual check for physical damage to the media container and evidence of media contamination before its use
   - For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities
   - The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media
   - For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement
   - Evidence that manufacturers’ specifications for using media are followed
Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement

Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotrophic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory’s written procedures

**Standard QSA.10.05.01**
The embryo laboratory has a method of tracking cryopreserved specimens.

**Rationale for QSA.10.05.01**
The embryo laboratory has an accurate and reliable method of tracking cryopreserved specimens ensuring positive identification of each cryopreservation container.

**Elements of Performance for QSA.10.05.01**

1. The embryo laboratory labels each cryopreservation container with the date the specimen was frozen and the patient’s name or unique identifier.

2. The embryo laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank.

3. The documentation for each liquid nitrogen storage tank used in the embryo laboratory includes the following:
   - The patient name or unique identifier
   - A description of each cryopreservation container’s contents
   - The freezing procedure used
   - The date each cryopreservation container was frozen
   - The type and location of the cryopreservation container
   - Final disposition or disposal of the cryopreserved specimen(s)

**Standard QSA.10.06.01**
The embryo laboratory uses policies and procedures for the receipt or transfer of cryopreserved specimens that maintain specimen identification and integrity.
Elements of Performance for QSA.10.06.01

1. If cryopreserved specimens are received or transferred to other facilities, the embryo laboratory has written policies and procedures for the receipt or transfer of cryopreserved specimens.

2. The embryo laboratory policies and procedures for the receipt or transfer of cryopreserved specimens include the following:
   - Methods to maintain specimen identification and specimen integrity
   - Methods of transportation
   - Method for verifying the identification and number of cryopreservation containers received or transferred

3. For transferred specimens, the embryo laboratory documents the following:
   - Freezing procedure used
   - Copies of patient release forms
   - Log sheets that accompany the cryopreserved specimens

4. The embryo laboratory follows its policies and procedures for the receipt or transfer of cryopreserved specimens.

Standard QSA.10.07.01

The embryo laboratory retains its records.

Elements of Performance for QSA.10.07.01

1. The embryo laboratory retains its records for 10 years beyond the date of final disposition or disposal of all specimens obtained during each patient’s assisted reproductive technology cycle, or longer if required by federal, state, or local laws.

2. The embryo laboratory retains its records on site for two years.

3. In the event of closure, the embryo laboratory makes provisions for records to be maintained for the time frames required.

   Note: Transfer of cryopreserved specimens to another facility constitutes final disposition or disposal for the transferring facility.

Standard QSA.11.01.01

On each day of patient testing, the laboratory verifies each hematology procedure and test parameter against known standards or controls within the range of clinically significant values.
Elements of Performance for QSA.11.01.01

4. Each individual performing manual cell counts performs one level of control for every eight hours of testing. The quality control results are documented.

5. Cell counts are tested in duplicate when performed using a hemocytometer.

6. For manual hematology tests, the laboratory defines written criteria for acceptable precision of duplicate samples.

7. For manual hematology tests, the laboratory adheres to criteria for acceptable precision of duplicate samples.

8. For manual determination of hemoglobin, the laboratory uses two levels of control for every eight hours of patient testing. The quality control results are documented.

Note: Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance.

Standard QSA.11.02.01

The laboratory’s coagulation testing provides accurate results.

Elements of Performance for QSA.11.02.01

1. The laboratory performs quality control testing across a range of clinically significant values on each day that it performs coagulation testing. The quality control results are documented.

2. For automated coagulation testing systems: The laboratory performs two levels of quality control material each eight hours of patient testing. The quality control results are documented.

Note: Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance.
3. **For automated coagulation testing systems:** The laboratory performs two levels of quality control material each time reagents change. The quality control results are documented.

4. **For manual coagulation testing systems (any coagulation test with a manual pipetting step):** The laboratory runs patient samples and quality control materials in duplicate.

5. **For manual coagulation testing systems (any coagulation test with a manual pipetting step):** The laboratory has predetermined limits of precision for the results of patient samples and quality control materials performed in duplicate.

6. **For manual coagulation testing systems (any coagulation test with a manual pipetting step):** Each staff who performs a test analyzes two levels of quality control materials before testing individual patient samples. The quality control results are documented.

7. **For manual coagulation testing systems (any coagulation test with a manual pipetting step):** Each staff who performs a test analyzes two levels of quality control materials each time reagents change. The quality control results are documented.

8. For each new lot number of thromboplastin reagent, the laboratory establishes the normal patient prothrombin time mean.

9. The laboratory reports results based on the current reagent lot number specifications.

   **Note:** For prothrombin time results, the international normalized ratio (INR) calculation incorporates the normal patient prothrombin time mean and the international sensitivity index (ISI) value specific to the lot of thromboplastin reagent in use.

10. **For manual coagulation testing systems (any coagulation test with a manual pipetting step):** The laboratory has written policies and procedures based on an approved clinical guideline to collect specimens for the performance of plasma-based coagulation assays.

†† Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document H21 (Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays).
Standard  QSA.12.01.01

The laboratory uses quality control practices and validation methods for histocompatibility testing.

Elements of Performance for QSA.12.01.01

1. The laboratory has written quality control practices and validation methods for histocompatibility, including clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed human leukocyte antigen (HLA)–specific antibodies.

2. The laboratory’s quality control practices and validation methods for histocompatibility are current.

3. The laboratory follows its quality control practices and validation methods for histocompatibility.

4. The laboratory assigns separate and unique identifiers to donor and recipient samples that clearly distinguish the donor from the recipient.

5. The laboratory screens and tests donors and recipients. Screens and tests include the following:
   - Human leukocyte antigen (HLA) typing on all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection
   - HLA typing on cells from organ donors referred to the laboratory

   Note: The laboratory makes a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

6. For immunologic reagents (for example, antibodies, antibody-coated particles, complement) that facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the laboratory monitors the efficacy of the methods with quality control procedures.

7. The laboratory checks each typing for disease-associated human leukocyte antigen (HLA) antigens using quality control materials to monitor the test components and each phase of the test system for acceptable performance.
8. The laboratory has a system in place for proper storage and maintenance of both recipient sera and reagents at an acceptable temperature range for sera and components, including a temperature alarm system and an emergency plan for alternative storage.

9. After compatibility is established between donor and recipient, a system exists to link the donor to the recipient.

   **Note:** Acceptable sources for histocompatibility testing practices include the current editions of the standards manuals for the American Society for Histocompatibility and Immunogenetics (ASHI) and federal regulations.

10. Reagent typing sera prepared in-house indicates source, bleeding date, identification number, reagent specificity, and volume remaining.

11. The laboratory uses human leukocyte antigen (HLA) antigen terminology that conforms to the most recent report of the World Health Organization (WHO) Committee on Nomenclature.

12. The laboratory uses a technique(s) that is established to define human leukocyte antigen (HLA) Class I and II specificities.

13. Each human leukocyte antigen (HLA) typing is checked by testing the following:
   - A positive quality control material
   - A negative quality control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results
   - Positive quality control materials for specific cell types (that is, T cells, B cells, and monocytes), when applicable

   **Note:** In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.

14. Each antibody screening is checked by testing the following:
   - A positive quality control material containing antibodies of the appropriate isotype for the assay
   - A negative quality control material
Standard QSA.12.02.01
Before transplantation is performed, the laboratory crossmatches potential recipients and donors using the most reactive and recent sera appropriate to the study or individual procedure performed.

Note: The laboratory makes every effort to screen out donors with any incompatibility potential.

Elements of Performance for QSA.12.02.01

1. The laboratory has written criteria for crossmatching, including the following:
   - Selecting patient serum samples for crossmatching
   - The preparation of donor cells or cellular extracts (for example, solubilized antigens, nucleic acids), appropriate to the crossmatch technique(s) performed

2. The laboratory follows its criteria for crossmatching.

3. The laboratory crossmatches potential recipients and donors before transplantation is performed. This crossmatching is documented.

   Note: For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, the laboratory has available results of final crossmatches before the kidney is transplanted.

4. The laboratory performs crossmatching with the most reactive sample collected within one month of testing. The crossmatching is documented.

5. The laboratory uses a technique(s) documented to have increased sensitivity when compared to the basic complement-dependent microlymphocytotoxicity assay for crossmatching.

6. The laboratory checks each crossmatch and compatibility test for human leukocyte antigen (HLA) Class II antigenic differences using quality control materials to monitor the test components and each phase of the test system for acceptable performance. The quality control results are documented.

7. If the recipient has had a sensitizing event, or his or her history is uncertain, the crossmatch is done with a serum sample collected within two days of the transplant.
8. For nonrenal transplantation, if human leukocyte antigen (HLA) testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances under which the emergency transplant was performed, if known.

**Note:** Records of the transplant must reflect any information provided to the laboratory by the patient’s physician.

**Standard QSA.12.03.01**
The laboratory performs human leukocyte antigen (HLA) serologic typing of both donor and recipient appropriate to the study or individual procedure performed.

**Elements of Performance for QSA.12.03.01**

1. The laboratory has written procedures for human leukocyte antigen (HLA) serologic typing of both donor and recipient appropriate to the study or individual procedure performed, which include the following:
   - Each HLA-A, -B, -C antigen is defined by using at least two or three different sera depending on whether monospecific or multispecific sera are used.
   - Each HLA-DR antigen is defined by using five antisera or three operationally monospecific antisera.
   - Using a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay
   - The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed
   - The selection of typing reagents, whether prepared in-house or commercially
   - Reagents used for histocompatibility typing that are adequate to define HLA-A, -B, and -DR specificities that are officially recognized by the most recent World Health Organization (WHO) Committee on Nomenclature
   - The assignment of HLA antigens
   - Antigen redefinition and retyping
   - Using a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens

2. The laboratory follows its procedures for human leukocyte antigen (HLA) serologic typing of both donor and recipient.

**Standard QSA.12.04.01**
The laboratory uses procedures for histocompatibility testing.
Elements of Performance for QSA.12.04.01

1. The laboratory has written procedures for histocompatibility testing, including the following:
   - Human leukocyte antigen (HLA) typing, antibody screening, compatibility testing, and crossmatching, to be performed for each type of cell, tissue, or organ to be transfused or transplanted
   - Testing protocols for deceased donor, living, living-related, and combined organ and tissue transplants
   - Testing protocols for patients at high risk for allograft rejection
   - The level of testing required to support clinical transplant protocols (for example, antigen or allele level)

2. The laboratory follows its procedures for histocompatibility testing.

Standard QSA.12.05.01
The laboratory uses procedures to screen individual sera from potential organ or tissue graft recipients through characterization of antibodies against histocompatibility antigens.

Elements of Performance for QSA.12.05.01

1. Appropriate to the study or individual procedure performed, the laboratory uses a panel for screening individual sera from potential organ or tissue graft recipients for characterization of antibodies against histocompatibility antigens to the level necessary to support clinical transplant protocol.

2. Appropriate to the study or individual procedure performed, the laboratory uses a panel that includes the major human leukocyte antigen (HLA) specificities and common splits.

Standard QSA.12.06.01
The laboratory performs mixed lymphocyte cultures or uses other recognized methods to detect cellular-defined antigens.

Elements of Performance for QSA.12.06.01

1. The laboratory has written criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens that include the following:
   - Viability of all suspensions exceeding 80% at the start of culture
   - A demonstrated lack of cytotoxic antibodies for sera used in media
Each mixed lymphocytic culture test includes an autologous control and unrelated control responders and stimulators.

Incubating and labeling techniques discriminate between positive and negative responses.

2. The laboratory follows its criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens.

**Standard QSA.12.07.01**
The laboratory validates interlaboratory reproducibility.

**Elements of Performance for QSA.12.07.01**

1. The laboratory has a written policy to participate in a cell exchange program that does the following:
   - Establishes valid interlaboratory reproducibility criteria
   - Documents performance levels
   - Takes and documents corrective action when indicated
   - Maintains a cumulative record for at least two years before survey
   - Provides that the director or supervisor performs and documents each review

**Note:** The laboratory participates in at least one national or regional cell exchange program, if available, or develops an exchange system with another laboratory in order to validate interlaboratory reproducibility.

2. The laboratory follows its policy for participating in a cell exchange program.

**Standard QSA.13.01.01**
Surgical specimens are sent to a pathologist for evaluation.

**Elements of Performance for QSA.13.01.01**

1. Surgical specimens are sent to a pathologist for evaluation unless exceptions are identified by the clinical staff.

2. The clinical staff, in consultation with a pathologist, decides when an exception to the submission of surgical specimens to pathology should be made using the following criteria:
   - The quality of care has not been compromised.
   - The surgical specimen removal is routinely verified by another clinically acceptable means.
The removal of the specimen is documented in an authenticated operative or other official report.  
The exception is authorized by law, the requirements of a training program, or the clinical staff laws or rules and regulations.  

(See also QSA.13.04.01, EP 1)

3. The pathologist and the clinical staff jointly determine and document, in writing, the categories of surgical specimens that require only a gross description and diagnosis. (See also QSA.13.04.01, EP 1)

Standard QSA.13.02.01
Surgical specimens are accompanied by supporting clinical information and preoperative and postoperative diagnoses to the degree known.

Elements of Performance for QSA.13.02.01
1. Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known.
2. Requests for examining surgical specimens are accompanied by supporting clinical information as indicated by patient history and laboratory policy.

Standard QSA.13.03.01
The laboratory documents its receipt of surgical specimens and maintains the identity of the specimens throughout processing and storage.

Elements of Performance for QSA.13.03.01
1. The laboratory documents its receipt of surgical specimens.
2. The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage.
3. The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage.

Standard QSA.13.03.03
The laboratory manages risks associated with tissues containing radionuclides.
Elements of Performance for QSA.13.03.03

1. The laboratory has written policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides.

2. The laboratory follows its policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides.

Standard QSA.13.04.01

Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Elements of Performance for QSA.13.04.01

1. Every surgical specimen receives a gross and microscopic evaluation and a diagnostic report, unless identified as an exemption. (See also QSA.13.01.01, EPs 2 and 3)

2. When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: He or she meets the qualifications for high-complexity testing personnel.

3. When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The laboratory delineates in writing the portions of the gross analysis that the individual is permitted to perform (for example, “May weigh, measure, and describe these types of tissue, but not section,” or “May only perform gross analysis of skin biopsies”).

4. When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual’s work is reviewed by the technical supervisor or qualified pathologist within 24 hours. The review is documented.

5. An individual qualified in anatomic pathology evaluates each microscopic section.

6. For Mohs testing, an individual qualified in anatomic pathology or a qualified dermatologist evaluates each microscopic section.

7. The diagnosis for each surgical specimen is made by or under the supervision of a qualified\*\*\* individual. R

8. The laboratory uses terminology for diagnoses from a nationally recognized, professionally accepted disease nomenclature (for example, the Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]). R

9. ☐ Cancer pathology reports use a synoptic format. R

**Standard QSA.13.05.01**

The laboratory manages hazards associated with the use of an electron microscope.

**Elements of Performance for QSA.13.05.01**

1. ☐ The laboratory has written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope.

2. The laboratory uses precautions related to radiation and electrical hazards of an electron microscope.

**Standard QSA.13.06.01**

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

**Elements of Performance for QSA.13.06.01**

1. A pathologist qualified\*\*\* in anatomic pathology assesses the staining quality (for example, equipment, methods, stains) of microscopic tissue sections to determine the stain’s ability to facilitate a diagnosis. The staining quality assessments are documented.

2. ☐ The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented.

\*\*\* Additional information can be found in Cancer Program Standards 2012: Ensuring Patient-Centered Care by the Commission on Cancer of the American College of Surgeons at http://www.facs.org/cancer/coc/programstandards2012.pdf.

Note: For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. For polymer-based immunohistochemical methods, a negative control is not required.

3. Each time of use for patient testing, the laboratory performs quality controls for each type of histologic stain used. The quality control results are documented.

   Note: Documentation may be contained in a dictated report or on a separate log.

Standard QSA.13.07.01
The laboratory retains histological specimens for patient care purposes.

Elements of Performance for QSA.13.07.01

1. Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are permanently identified, stored for preservation purposes, and organized for retrieval.

2. Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are retained in accordance with law and regulation and as defined by organization policy.

   Note 1: Minimum retention requirements in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) regulations are defined as follows:
   - Microscopic slides, including stained slides, are retained for at least 10 years.
   - Paraffin blocks are stored for at least two years from the date of the examination.
   - Gross tissue specimens are retained for at least seven days after required microscopic sections are examined and reports are reviewed and signed.

   Note 2: Individual state law and regulation for retention requirements may vary. The most stringent guidelines should be followed.

Standard QSA.13.08.01
The histopathology laboratory conducts surveillance of patient results and related records as part of its quality management plan.

Elements of Performance for QSA.13.08.01

1. The histopathology laboratory has written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report.
2. ☐ The histopathology laboratory conducts an investigation and takes corrective action on disparities that exist between an initial intraoperative consultation and a report of pathology diagnosis. The disparities and corrective action are documented.

Standard QSA.14.01.01
The laboratory provides for the accuracy of immunology tests, including syphilis serology, through the use of quality controls and tests for antigen reactivity.

Elements of Performance for QSA.14.01.01

1. ☐ For immunology tests, including syphilis serology, the laboratory uses quality control materials that include a challenge of the extraction phase of the test, if applicable. The quality control results are documented.

2. ☐ The laboratory tests immunology test components for reactivity, if applicable. The reactivity results are documented.

Note: Examples of test components that require a test for reactivity include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded controls.

3. ☐ The laboratory determines, in writing, the reactivity patterns of quality control materials for immunology tests before or concurrently with test performance, if applicable.

Standard QSA.14.02.01
The laboratory performs syphilis testing with equipment, reagents, quality control materials, and techniques.

Elements of Performance for QSA.14.02.01

1. The laboratory’s syphilis testing conforms to manufacturers’ specifications, including techniques, equipment (for example, rotator speed), room temperature, quality control materials, and reagent drop size.

2. ☐ If required by the manufacturer, the laboratory tests a weak reactive quality control material for syphilis testing. The quality control result for weak reactive is documented.

Standard QSA.15.01.01
The laboratory uses written policies and procedures for molecular testing.
Elements of Performance for QSA.15.01.01

1. The laboratory has written policies and procedures for molecular testing. The laboratory’s policies and procedures for molecular testing address the following:

2. Appropriateness of testing.

   **Note:** For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).

3. Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing.

4. Prevention of sample degradation. *(See also DC.01.01.01, EP 1)*

5. Documentation of all nucleic acid reagents, including probes and primers, used in a particular test.

6. The quality and quantity of nucleic acid required for a particular test.

7. Investigation and corrective action for internal controls that fail to amplify.

8. Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal).

9. Investigation of discrepant results between different methods.

10. Reuse of patient specimens for quality control purposes.

11. Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production).

12. The criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal).

13. Verification of patient nucleic acid integrity and labeling.

14. Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors.
15. The laboratory follows its policies and procedures for molecular testing.

**Standard QSA.15.02.01**

The laboratory’s verification studies for molecular testing include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.

**Elements of Performance for QSA.15.02.01**

1. The laboratory’s verification studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay.

2. The laboratory’s verification studies for molecular testing include specimens representing the scope of reportable results.

3. The laboratory performs verification studies for molecular testing. The verification studies are documented.

**Standard QSA.15.03.01**

The laboratory establishes quality control limits, reference ranges, and reportable ranges for molecular testing.

**Elements of Performance for QSA.15.03.01**

1. The laboratory establishes quality control limits, reference ranges, and reportable ranges to provide molecular test results with meaningful clinical applications.

2. The laboratory establishes quality control limits for quantitative molecular tests that are strict enough to promote precision and accuracy for reliable patient test results.

3. For qualitative tests, the laboratory establishes a threshold value to distinguish positive from negative results prior to patient testing; threshold values are then verified for each new lot and every six months thereafter, or at a frequency consistent with laboratory policy or manufacturers’ instructions, if more stringent.
Standard QSA.15.04.01
The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

Elements of Performance for QSA.15.04.01

1. The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing.
2. Molecular testing procedures are consistent with current practice standards for this or similar methodologies, and are at least as rigorous as those required or recommended by the manufacturer.
3. The laboratory follows its quality control procedures for molecular testing.
4. For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented.
5. For each electrophoretic run, the laboratory uses the following markers:
   - Molecular weight markers of known size that span the expected range of band distribution
   - Visual or fluorescent markers to establish the endpoint of electrophoresis

Standard QSA.15.05.01
The laboratory’s molecular testing reports include specific testing information.

Elements of Performance for QSA.15.05.01

The laboratory reports for molecular testing include the following information:

1. The testing methodology used.
2. The limitations of the method used.
3. Any interpretation of findings.
4. Any recommendations for additional testing.
5. For assays developed by the laboratory, the laboratory reports for molecular testing include a statement that the assay was developed by the laboratory.
6. The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic specific reagents (ASR).
Note: Federal regulations require that the following disclaimer accompany the test result on the report: “This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the US Food and Drug Administration (FDA).”

7. Molecular testing reports filed in the patient’s clinical record that require specific interpretation are authenticated by the individual qualified by the Clinical Laboratory Improvement Amendments (CLIA ’88) to make the interpretation.

Standard QSA.16.01.01
The laboratory uses policies and procedures for molecular genetic testing.

Elements of Performance for QSA.16.01.01

1. The laboratory has written policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling.

2. The laboratory has written policies and procedures for molecular genetic testing that address the reporting of results when additional information necessary for interpreting test results is not received by the laboratory.

   Note: Additional information might be required to provide for accurate test interpretation and reporting of results.

3. The laboratory has written policies and procedures for molecular genetic testing that establish turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner).

4. The laboratory follows its policies and procedures for molecular genetic testing.

Standard QSA.16.02.01
Molecular genetic testing reports include specific testing information.

Elements of Performance for QSA.16.02.01

The laboratory reports for molecular genetic testing include the following information:

1. Indication for testing.

2. List of genes or alleles tested.
3. Any recommendations for referral to a genetic counselor.
4. Detection rate of the test.
5. Standard nomenclature for genes and mutations.
6. Clinical implications of any detected mutation(s).

**Standard QSA.17.01.01**
The laboratory uses parasitology reference materials and a calibrated measuring device for determining the size of ova or parasites.

**Elements of Performance for QSA.17.01.01**

1. The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites.
2. The laboratory makes a calibrated ocular lens for ova and parasite size measurement available to staff performing testing.
3. The procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites are available for staff performing testing.
4. The laboratory follows its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites.
5. The laboratory makes parasitology reference materials available to staff performing testing.

*Note: Examples of reference materials include textbooks with photographs, collections of previously stained slides, preserved gross specimens of identified parasites, and slides for proficiency testing.*

**Standard QSA.17.01.03**
The laboratory stores and evaluates reagents for parasitology.

**Element of Performance for QSA.17.01.03**

1. The laboratory determines the specific gravity of zinc sulfate solutions used for the concentration of fecal specimens (1.18 for fresh specimens and 1.20 for formalin-fixed specimens).
Standard QSA.17.02.01
The laboratory performs quality control testing for parasitology permanent stains.

Elements of Performance for QSA.17.02.01

1. The laboratory uses quality control materials to verify parasitology permanent stains that demonstrate typical staining characteristics.

   \textit{Note:} Quality control materials can consist of fecal samples with parasites or added leukocytes to demonstrate staining characteristics.

2. The laboratory performs quality control testing on parasitology permanent stains each month of use, or according to laboratory policy if more stringent. The quality control results are documented.

Standard QSA.18.01.01
Provider-performed microscopy (PPM) procedures are performed using a brightfield or a phase/contrast microscope.

Element of Performance for QSA.18.01.01

1. The laboratory performs provider-performed microscopy (PPM) procedures using a microscope limited to a brightfield or a phase/contrast microscope.

Standard QSA.19.01.01
When the laboratory uses in vivo or in vitro radioisotopes, it uses procedures that are safe to patients and staff and that provide accurate results.

Elements of Performance for QSA.19.01.01

1. The laboratory has written procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.

   \textit{Note:} For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01.

2. The laboratory addresses the following related to radiobioassay tests:
   - Performing background counts
   - Calibrating equipment

\textsuperscript{***} For more information on competency regarding provider-performed microscopy (PPM) procedures, please refer to the “Human Resources” (HR) chapter, Standard HR.01.06.01.

\textsuperscript{††} For guidelines, see the Nuclear Regulatory Commission requirements and National Council on Radiation Protection and Measurements.
- Safety measures for decontamination
- Handling radioactive isotopes
- Handling radioactive waste
- Posting for the presence of radioactive materials
- Monitoring the radiation area (for example, wipe tests)

(See also EC.02.02.01, EP 6)

**Note:** For activities to minimize risks associated with radioactive materials, please refer to the “Environment of Care” (EC) chapter, Standard EC.02.02.01.

3. The laboratory follows its procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.

**Standard QSA.19.02.01**

The laboratory uses a quality control system for in vivo testing.

**Elements of Performance for QSA.19.02.01**

1. **For in vivo testing:** The laboratory has a quality control system that addresses safety and proper equipment performance.

2. **For in vivo testing:** The laboratory maintains records on radioactive isotopes and radiopharmaceuticals from the point of entry into the laboratory to administration and final disposal.

3. **For in vivo testing:** The laboratory documents in department records the following information for radioactive isotopes:
   - Identity
   - Date received
   - Method of receipt
   - Activity
   - Storage
   - Preparation
   - Handling
   - Identity of recipients
   - Dates administered
   - Disposal

4. **For in vivo testing:** The laboratory identifies radioactive isotopes and dose verification before administration.
5. **For in vivo testing:** The laboratory prepares radiopharmaceuticals according to manufacturers’ specifications.

6. **For in vivo testing:** The laboratory standardizes equipment performance by using radiation standard sources with energies equivalent to those radioactive isotopes used in patient studies.

### Standard QSA.20.01.01

The laboratory obtains and maintains information and records of complete semen analysis.

### Elements of Performance for QSA.20.01.01

The collection information for semen analysis includes the following:

1. ☑️ Method of collection. The information is documented.
2. ☑️ Type of specimen container. The information is documented.
3. ☑️ Days of abstinence. The information is documented.

The sample quality for semen analysis includes the following:

4. ☑️ Collection or transport problems (for example, exposure to temperatures, incomplete specimen). The information is documented.
5. ☑️ Time of specimen receipt and analysis. The information is documented.
6. ☑️ Abnormalities of liquefaction. The information is documented.

7. ☑️ Semen analysis information includes the following, as applicable: Characteristics of semen specimens (for example, contaminants, erythrocytes, viscosity, appearance, volume, pH). The information is documented.

8. ☑️ Semen analysis information includes the following, as applicable: Sperm number, motility, and progression. The information is documented.

9. ☑️ Semen analysis information includes the following, as applicable: Method for sperm morphology classification, including stains, as required. The information is documented.

10. ☑️ Semen analysis information includes the following, as applicable: Positive and negative controls with each assay for quantitative biochemical tests performed on the semen. The quality control results are documented.
11. Semen analysis information includes the following, as applicable: The evaluation of semen specimens based on approved clinical guidelines. The results are documented.

**Standard QSA.21.01.01**
The laboratory has methods for virology testing.

**Element of Performance for QSA.21.01.01**

1. The laboratory has methodologies that are designed to isolate and/or identify viruses.

**Standard QSA.21.02.01**
The laboratory uses cell controls and processes to assess the accuracy of virology testing results.

**Elements of Performance for QSA.21.02.01**

1. The laboratory simultaneously incubates either a cell substrate control or uninoculated cells as a negative control material with patient testing.

The virology laboratory documents the following:

2. Cell lines used for the virus being isolated.
3. Control checks of maintenance media.
4. Sterility checks.
5. Reagent checks for toxicity to cell lines.
6. Controls for neutralization tests.
7. Controls for hemagglutination inhibition tests.
8. Controls for immunoassays.
9. Controls for direct immunofluorescence tests.
10. Controls for indirect immunofluorescence tests.

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Additional information can be found in the current editions of Clinical and Laboratory Standards Institute (CLSI) document POCT10 (Physician and Nonphysician Provider-Performed Microscopy Testing) and World Health Organization (WHO) Laboratory Manual for the Examination and Processing of Human Semen.
11. ⚫ The laboratory performs daily quality control for virology stains. The quality control results are documented.

**Standard QSA.21.03.01**
The laboratory maintains records of virology testing processes.

**Elements of Performance for QSA.21.03.01**
The laboratory maintains records on the following:

1. Cell lines used to isolate viruses.
2. Test methods used to detect or identify viruses.
3. Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]).

**Standard QSA.21.04.01**
For serodiagnostic tests for viral disease, the laboratory tests components for reactivity.

**Elements of Performance for QSA.21.04.01**

1. ⚫ For serodiagnostic tests for viral disease, the laboratory determines the reactivity patterns of the quality control materials before or concurrent with performance of the test and before the reporting of individual patient test results. The reactivity patterns are documented.

2. ⚫ For serodiagnostic tests for viral disease, the laboratory tests components for reactivity. The reactivity patterns are documented.

   **Note:** Examples of such components include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded quality control materials.

3. ⚫ For serodiagnostic tests for viral disease, the laboratory performs quality control testing, including internal and external controls. The quality control results are documented.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

Proficiency Testing

If there is a change with the laboratory’s proficiency testing provider within less than a full calendar year, is there documentation that CMS or The Joint Commission were notified? (QSA.01.01.01)

**TIP:** Document every single piece of data surrounding proficiency testing. Use an investigation form provided by the proficiency testing provider or The Joint Commission website. Investigations must be performed when:
- There are unacceptable results
- Submission was late and the score is zero
- The laboratory did not participate in the event and the score is zero
- There was a lack of consensus and the score is ungradable

Investigation must include potential causes and provide evidence of review.

When adding new regulated analytes, is there documentation of proficiency testing enrollment for the remainder of the year? (QSA.01.01.01, QSA.02.01.01)

**TIP:** Proficiency testing should begin as soon as possible after a new method is introduced in the laboratory. When it is not possible to subscribe to appropriate events, attempts should be made to obtain previously reported events from vendors to perform a self-assessment.
TIP: Corrective action is separate from investigation. Establish criteria for initiating both actions and clearly document every step taken for correcting and investigating unsatisfactory and unsuccessful proficiency testing results.

How often does the laboratory director or technical supervisor (i.e., immunohematology) review the following? (QSA.01.02.01)
- Attestations for all signatures on running proficiency testing
- Proficiency testing provider program reports
- Overall review of proficiency testing results prior to submission

Are attestations signed by the staff who performed the testing at the time the testing was completed? (QSA.01.02.01)

TIP: Create a schedule that includes all staff that perform the proficiency test. Periodically assess staff competency when running the test to verify that proficiency testing specimens are treated the same way as a patient’s specimen. As such:
- Never run in duplicates unless patient specimen is run in duplicates.
- Never run on multiple instruments before reporting results to the proficiency testing provider.

Are all proficiency testing specimens run and reported on primary instruments using primary methods? (QSA.01.03.01)
TIP: Additional proficiency testing reminders:

- Proficiency testing must be performed for each regulated analyte for each CLIA certificate and the testing must be performed only the number of times a patient specimen is tested.
- All laboratories subject to CLIA regulations are no longer allowed to test and report proficiency testing specimens from a secondary/backup instrument during the primary proficiency testing event.
- When there are multiple instruments used to report the results of the same regulated analyte, one of the instruments must be designated as the primary instrument and used to analyze proficiency test specimens. Correlation of results produced on the first instrument with those produced on other instruments must be conducted every six months.
- Proficiency test specimens may be tested on instruments not designated as the “primary” instrument providing the results are produced after the closing date for submission of proficiency test results for the specific event.

Does the pathologist who examines gynecological cytology specimens participate in a CMS-approved proficiency program for gynecological cytology? (QSA.01.01.01)

TIP: Gynecological cytology is the only proficiency requirement required by CLIA regulations for a pathologist. Alternate surveys cannot be used to substitute for the gynecological cytology proficiency participation requirement.

Is all proficiency testing documentation retained for a minimum of two years? (QSA.01.01.01, QSA 01.02.01)
**TIP:** While proficiency testing is not required for waived methods, it is good practice to perform proficiency tests on waived methods as part of the overall quality assurance program and as part of the competence assessment program.

**Quality Control**

**TIP:** Always review and check additional quality control requirements for each specialty and subspecialty. The Joint Commission currently surveys manufacturer suggestions and recommendations as requirements.

How does the laboratory assess the following analytical performances? (QSA.02.01.01)

- Accuracy and precision
- Analytical sensitivity
- Quality control reference ranges validation
- Calibration and verification
**TIP:** Have a schedule and post due dates of validating quality control results, calibration, and verification. Consider the following unique situations:

- Semiannual calibration verification is not required if there are three or more calibrators and the test is calibrated at least every six months. Document all calibration verification results.

- For automated cell counters, calibration verification requirements are met if the laboratory follows manufacturer’s instructions for instrument operation and the laboratory tests two levels of quality control materials each day of patient testing, provided the laboratory’s quality control criteria are met.

- Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use.

- Laboratories may use linearity testing to meet the requirements for semiannual calibration verification as long as it includes a minimum of three points—a low, middle, and high value.

- Calibration verification is not required for coagulation methods. Materials are not readily available to perform such studies.

**TIP:** The laboratory director, technical consultant, or technical supervisor must determine the most appropriate validation process through discussion with the manufacturer and other technical resources. Deviation from the manufacturer’s suggested protocol must be approved in writing by the laboratory director.

What are the criteria for establishing the frequency of running quality control materials for each instrument, equipment, and reagent? (QSA.02.04.01, QSA.02.06.01)
What type of alternative methods of quality control are established when no quality control materials are available? (QSA.02.06.01, QSA.02.10.01)

**TIP:** When quality control materials or calibration is required at a six-month interval, six months means six months within the date of the last run, which is plus or minus 15 days.

How many test systems implement an Individualized Quality Control Plan (IQCP)? (QSA.02.04.01)

**TIP:** Verify that all IQCPs include the three required components and address all phases of testing (preanalytic, analytic, and postanalytic). Remember all specialties and subspecialties except histopathology and cytology are eligible for IQCP.

Do all established reportable ranges align with calibration verification data? (QSA.02.03.01)

How are correlation studies performed on new instruments and methodologies? Are the procedures available to all staff? (QSA.02.08.01)
**TIP:** Correlations are required when the same tests are performed using different instruments or in different locations of an organization. Correlations may be performed with another laboratory to determine the accuracy and reliability of the new method. The number of specimens used for correlation is determined by the laboratory director.

Are staff informed and adequately trained on acceptable parameters defined in the laboratory policy and how to verify results within the established parameters? (QSA.02.06.01, QSA.02.07.01)

How does the laboratory determine that quality control materials are run in the same manner as patient specimens? (QSA.02.09.01)

**TIP:** When using on-board controls, provide a record that the quality control specimens follow the same physical pathway as a patient specimen. Instrument manuals and manufacturer’s instructions are good starting points to demonstrate the quality control materials pathway.
**TIP:** Criteria for review should be defined. Questions to consider:

- What requires immediate action?
- What must be referred to a supervisor?
- What requires a corrected report?
- What must be reported to the laboratory director?
- How and by whom are work records, equipment records, quality control summaries reviewed?
- At what frequency (but no less often than monthly)?

If the same quality control materials are used for instruments with common analytes (i.e., Hgb on both the hematology and blood gas instruments), are proper criteria (i.e., same lot number) established and evaluated? (QSA.02.08.01)

When daily review of quality control data is delegated, what is the laboratory policy for director/supervisor review of the overall surveillance performed? (QSA.02.11.01)

**TIP:** Check the accuracy of patient results on the patient charts and the laboratory information system. Discrepancy and delayed transfer of data must be resolved.

Does the laboratory have established procedures for laboratory-developed tests? (QSA.02.01.01)
**TIP:** Train staff on laboratory-developed tests and modification of a test.
- Any deviation from the FDA–approved process or specimen type currently creates a test of high complexity.
- Testing of a specimen type not validated by the manufacturer constitutes a modification of an FDA process. The test must be validated as a high complexity method, and all of the requirements for high complexity testing will apply to the modified method.
- Remember that personnel requirements to high complexity testing differs from those performing moderate complexity testing.

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**Autopsy Services**

What are the qualifications of the staff responsible for performing autopsies? (QSA.03.01.01)

**TIP:** Post the required time frame for documenting preliminary and final clinical autopsy reports in the patient’s clinical record.

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**Bacteriology, Mycobacteriology, and Mycology**

What is the laboratory’s policy for checking quality controls of media? Does it incorporate visual checks upon receipt, and at what frequency? (QSA.04.01.01, QSA.04.04.01, QSA.04.06.01)
Do the quality control procedures for microbiological reagents, disks, and stains use positive and negative controls for each new batch, new lot number, and shipment? (QSA.04.01.01)

**TIP:** Streamlined quality control for a microbial identification system requires IQCP. Document all quality control procedures including all modifications as a result of IQCP implementation.

What are the criteria used for determining and measuring minimum inhibitory concentration (MIC) endpoint or zone size? If the laboratory adopts validated criteria from other sources (i.e., FDA, CLSI, EUCAST), how does the laboratory staff access these sources and are they the most current versions? (QSA.04.02.01, QSA.04.04.01)

**TIP:** Create a document log of the different quality control requirements as applicable to each media and isolates.

Post the complete description of CMS antimicrobial susceptibility testing requirements in the laboratory. (Available from the Centers for Medicare & Medicaid Services [CMS] Operations Manual, Appendix C.)

Where can staff locate the laboratory procedure for positive blood culture workups? Does the procedure incorporate checking for timeliness of the workup if the microbiology laboratory is not staffed for 24 hours a day, 7 days a week? (QSA.04.07.01)
Does the laboratory have clearly written procedures for the following? (QSA.04.03.01):
- Requirements for quantitative cultures such as urine colony counts
- Gram stain quality control
- Use of antibiogram data

How often does the laboratory check and record CO₂ levels of incubators? (QSA.04.05.01)

**Blood Transfusion Service and Donor Center**

When was the last time all laboratory policies and procedures on blood transfusion were reviewed? (QSA.05.01.01)

What is the laboratory requirement for minimum inventory of blood and blood components? How are the minimum inventory requirements established? (QSA.05.02.01)

How does the laboratory handle unused blood and blood products? (QSA.05.03.03)

**TIP:** Incorporate utilization reports and statistics to account for unused blood and blood components previously issued for transfusion to the blood bank.
What is the laboratory’s plan during an emergency power outage that could affect all storage systems and equipment used for storage and administration of blood and blood products? (EC.02.05.03, QSA.05.04.01, QSA.05.04.03)

**TIP:** Conduct drills and regularly check staff competency on handling the following possible emergencies:
- Disaster planning and unplanned power outage
- Suspected and confirmed transfusion reactions
- Emergency release of blood products
- Potentially infected blood and blood components
- Deviation from any procedures

How often does the laboratory check temperature alarms and equipment (i.e., blood warmers, centrifuge) for possible malfunction? (QSA.05.04.03)

**TIP:** Educate staff on the required temperature ranges for specific blood and blood components.

Do the laboratory procedures incorporate visual inspection of blood and blood products upon receipt, storage, and release? (QSA.05.03.01)
**TIP:** The transfusion service director has oversight of blood administration policies, processes, and procedures. Check the “Human Resources” (HR) chapter to verify the qualifications of the transfusion service director.

What is the laboratory’s policy for reviewing validation reports of computer systems for ABO incompatibility? Is the policy consistent with manufacturer recommendations and laboratory procedures? (QSA.05.09.01, QSA.05.09.03)

What type of unique identifier is used by the laboratory for both recipient and donor blood? Are they validated to prevent mislabeling? (QSA.05.10.01, NPSG.01.01.01)

Are the staff properly trained on procedures for the following? (HR.01.06.01, QSA05.02.01, QSA.05.13.01, QSA.05.25.01)
- RhIG policies, procedures, and administration, if applicable
- Blood product acquisition, testing, and disposition records
- Therapeutic phlebotomy or donor center if applicable

Is there documentation that the patient vitals were monitored as required by policy? (QSA.05.17.01, QSA.05.18.01)
Clinical Chemistry

How does the laboratory detect potential carryover for chemistry instruments and analyzers? (QSA.06.04.01, QSA.06.04.03)

Does the laboratory use on-board quality control materials? (QSA.02.10.01, QSA.06.01.01, WT.05.01.01)

**TIP:** When using on-board controls, provide record that the quality control specimens follow the same physical pathway as a patient specimen. Instrument manuals and manufacturer’s instructions are a good starting point to demonstrate the quality control materials pathway.

What is the laboratory policy for running quality controls for blood gas analyzers? Does the time and frequency of running quality control materials meet the minimum requirement of running all three levels per day of patient testing AND with at least one level every 8 hours? Does the laboratory implement IQCP for any changes in the type and frequency of quality control being referenced? (QSA.02.04.01, QSA.06.02.01)
**TIP:** Specify the time for running the specific level of quality control materials for blood gas instruments. Quality control materials should be run at least 15 minutes before or after the 8-hour mark, providing a 30-minute window. If there are any changes in the required frequency of quality control, check the laboratory’s IQCP records to account for all risks identified in running less frequent quality controls.

Is the laboratory procedure for running calibration procedures consistent with manufacturers’ recommendations or instructions? (QSA.02.02.01, QSA.02.03.01)

**TIP:** Use charts to evaluate the following:
- Periodic review of instrument tubing and filters
- Quality control checks of pipettes, measuring devices, and analytical balances
- Thermometer calibration and regular room temperature checks

Review the “Environment of Care” (EC) chapter for additional requirements applicable to chemistry instruments.

**Clinical Microscopy**

What is the laboratory’s required time frame for testing and reporting fresh urine specimens and how does the laboratory maintain the specimens’ integrity? (QSA.07.01.01)
**Cytology**

Are all cytology screening staff licensed and do they meet federal and state qualifications? (HR.01.02.03, QSA.08.01.01)

Is the number of cytotechnologists adequate to handle the volume of testing without exceeding the maximum allowable workload limit per staff? (QSA.08.04.01)

How are initial screening and determination of specimen adequacy counted in the workload limit? (QSA.08.04.01)

**TIP:** Assess workload limit every six months. Educate staff every reassessment regarding workload limit and how criteria are established for the workload limit of all primary screeners, including pathologists.

What are the criteria for rejecting cytology specimens submitted in the laboratory? (QSA.08.03.01, QSA.08.05.01)
**TIP:** List common criteria to define unacceptable cytology specimens. Create a separate list of criteria for establishing unsatisfactory cytology specimens.

Is there a laboratory procedure that identifies slides that are not successfully processed by automated screening? (QSA.08.08.01)

**TIP:** Follow automated processing of cytology specimens to identify any discrepancy in the procedure that may cause unsuccessful processing.

How does the laboratory complete reports of non-gynecological slides and specific gynecological slides when the technical supervisor is not available to confirm and documents review? (QSA.08.07.01)

**TIP:** Educate staff on established criteria for the following situations:
- Amending cytology screening reports
- Time frame for notifying responsible clinician on amended screening reports
- Gynecologic slides requiring pathologist’s interpretation
- Rescreening qualifications
How does the laboratory prevent cross-contamination (processing and staining)? (QSA.08.05.01)

What is the frequency of assessing the quality of cytology stains, and does this reflect laboratory policies and procedures? (QSA.08.05.01)

What is the acceptable discrepancy rate between cytological interpretations to their corresponding histological findings? How are the discrepancies resolved? (QSA.08.06.03)

Cytogenetics

How does the laboratory track each cytogenetic specimen through the entire testing process (preanalytic, analytic, and postanalytic phase)? (QSA.09.02.01)

**TIP:** Walk through each step of cytogenetic specimen processing and evaluate how sample identification is accurately retained throughout the testing process. If there is a potential gap that may cause mislabeling, reevaluate the process and implement process improvement.

How does the laboratory establish the criteria for counting cells to meet its quality control and testing procedures? (QSA.09.03.01)
How are the laboratory staff informed and educated on the use of the International System for Cytogenetic Nomenclature? (QSA.09.05.01)

**TIP:** Post the laboratory’s retention time requirements for all materials used for cytogenetic case studies.

**TIP:** Post the laboratory’s time frame requirement for reporting preliminary and final results of various cytogenetic analysis.

How does the laboratory track and improve the turnaround times of chromosomal analysis? (QSA.09.07.01)

**Embryology**

How does the laboratory perform quality control checks of embryology media it uses? (QSA.10.04.01)

**TIP:** Quality control requirements may vary for various media. Check the use of each media and tailor quality control requirements for its specific use.
What type of unique identifier is used for labeling embryo laboratory specimens? (QSA.10.05.01)

What is the laboratory’s retention policy for embryology specimens and related records? (QSA.10.07.01)

**Hematology and Coagulation**

What is the established time frame for running the two levels of quality control materials for determination of hemoglobin? (QSA.11.02.01)

**TIP:** Specify the time for running quality control materials. Quality control materials should be run at least 15 minutes before or after the 8-hour mark, providing a 30-minute window.

**Histocompatibility**

What is the laboratory’s policy for periodic antibody screening and crossmatch of potential transplant recipients? (QSA.12.02.01)
What type of unique identifier does the laboratory use to distinguish the donor from the recipient? (QSA.12.01.01)

**TIP:** Review the “Environment of Care” (EC) chapter for proper equipment temperature, alarm system, and emergency plan requirements for storage of both recipient antisera and reagents.

What is the laboratory’s policy for screening donors for possible incompatibility prior to final sign-off for transplant procedures? (QSA.12.02.01)

**TIP:** Review the “Transplant Safety” (TS) chapter for more specific requirements of policies and procedures for safe tissue transplantation. Coordinate with other non-laboratory departments involved as needed.

**Histopathology**

Are there any exceptions for not sending surgical specimens for pathologist review? (QSA.13.01.01)

**TIP:** Clearly establish criteria for pathologist review of surgical specimens. Post the lists of criteria in the histopathology laboratory.
How do the laboratory documents support clinical information for examining surgical specimens? (QSA.13.02.01)

How are surgical blocks and slides labeled? (QSA.13.01.01, QSA.13.02.01, QSA.13.03.01)

Who reviews the quality of histologic stains, and how are the quality control checks recorded? (QSA.13.06.01)

If nonpathologists examine surgical specimens, how are they supervised and what are the qualifications of both the examiner and the supervisor? (QSA.13.04.01)

**TIP:** The surgical specimen examiner must meet the qualifications for high-complexity testing personnel.

What is the laboratory’s retention policy for histological specimens and related records? (QSA.13.07.01)
**Immunology and Syphilis Serology**

Are the manufacturer’s specifications for running quality control materials consistent with the laboratory policies and procedures? (QSA.02.06.01, QSA.14.01.01, QSA.14.02.01)

What are the different quality control requirements for quantitative versus qualitative testing? Are quality control ranges established and available for reference by the testing personnel? (QSA.02.06.01, QSA.14.01.01)

**TIP:** Make a “cheat sheet” of all immunology and serology testing and include quality control requirements and ranges.

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**Molecular Testing**

How do the laboratory policies and procedures for molecular testing address the following (QSA.15.01.01):

- Extraction of nucleic acids (genetic material) from the sample
- Amplification (or multiplication) of the number of genetic sequences
- Detection of the copies of genetic sequences following amplification

If applicable, how is the reference laboratory selected? (LD.04.05.13)
**TIP:** Review the “Leadership” (LD) chapter for the laboratory director’s responsibility in reviewing reference laboratories. Establish and maintain records of criteria uses for selecting a reference laboratory for molecular testing, including records of accreditation and CLIA certificates.

What are the different quality control requirements for quantitative versus qualitative molecular testing? Are quality control ranges established and available for reference by the testing personnel? (QSA.15.01.01, QSA.15.03.01)

How does the laboratory prevent nucleic acid contamination in all areas of the laboratory and in all phases of testing? (QSA.15.01.01)

What information is included in the molecular testing reports? Is it specific for each methodology? (QSA.15.05.01)

**TIP:** Make a “cheat sheet” of all molecular testing performed in the laboratory and outline all information required for reporting results of each test. Post the information in the molecular testing section of the laboratory.
Does the laboratory have established procedures for laboratory-developed tests? (QSA.02.01.01)

**TIP:** Review Appendix B on laboratory-developed tests (LDT) from this manual. Appendix B lists all standards applicable for LDTs.

### Molecular Genetics

How does the laboratory capture recommendations from genetic counselors for molecular genetic testing requests? (QSA.16.01.01)

What additional information is provided for accurate interpretation of the molecular genetic testing report? How is this additional information established, and is it specified in the laboratory policies and procedures? (QSA.16.02.01)

### Parasitology

What parasitology reference materials are available for laboratory staff performing testing? (QSA.17.01.01)

How often does the laboratory perform quality control testing on parasitology stains? (QSA.17.02.01)
Provider-Performed Microscopy Procedures

What are the competency requirements for personnel performing provider-performed microscopy (PPM)? (HR.01.06.01)

**TIP:** Create a document log of competency assessment for each PPM procedure.

### TIP: Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived Testing and PPMP (Note: PPM tests are not waived)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Use 6 methods (if applicable)</td>
</tr>
<tr>
<td></td>
<td>1. Blind testing</td>
</tr>
<tr>
<td></td>
<td>2. Direct observation of routine testing</td>
</tr>
<tr>
<td></td>
<td>3. Monitoring of QC performance by each user</td>
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<tr>
<td></td>
<td>4. Problem solving skills</td>
</tr>
<tr>
<td></td>
<td>5. Direct observation of instrument checks</td>
</tr>
<tr>
<td></td>
<td>6. Monitoring result reporting</td>
</tr>
<tr>
<td>Initial Training and Annual Assessment</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Semiannual in the first year</td>
</tr>
<tr>
<td>Signatures</td>
<td>Both the director/supervisor/consultant <strong>AND</strong> the employee must sign that the individual has received training and is competent prior to performing testing independently.</td>
</tr>
</tbody>
</table>

Radiobioassay

How does the laboratory track all radioactive isotopes from the point of entry into the laboratory to its final disposition? (QSA.19.01.01)
What is the equipment used for in vivo testing, and what are the laboratory’s quality control procedures for maintaining its accurate performance for patient testing? (QSA.19.02.01)

**Semen Analysis (Andrology)**

What are the laboratory’s quality control measures for semen analysis? (QSA.20.01.01)

What information is included in the laboratory’s semen analysis? Is the required information for semen analysis consistent with what is stated in the laboratory policy? (QSA.20.01.01)

**TIP:** Evaluate laboratory procedures for the collection of specimens for semen analysis to make sure that patients and testing personnel understand clearly all instructions for accurate testing.

**Virology**

What types of internal and external quality controls are used for serodiagnostic tests for viral diseases? (QSA.21.04.01)
**TIP:** Remember to simultaneously incubate a cell substrate control or uninoculated cell as negative quality control with patient testing when using cell cultures to isolate or identify viruses.

What is the required documented information when using cell controls to assess accuracy of virology testing results? (QSA.21.02.01)
Written Documentation Checklist
This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. (Note: Documentation can be on paper or in an electronic format.)

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA.01.01.01, EP 1</td>
<td>The laboratory participates in a Centers for Medicare &amp; Medicaid Services (CMS)—approved proficiency testing program* that meets regulatory requirements for variety and frequency of testing.** (See also LD.04.05.07, EP 4) *For information on current proficiency testing providers, see <a href="http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp">http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp</a>. **For more information on proficiency testing, see <a href="http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html">http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html</a>.</td>
<td></td>
</tr>
</tbody>
</table>
| QSA.01.02.01, EP 2 | The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action for the following:  
- Individual unacceptable proficiency testing results  
- Late submission of proficiency testing results (score is zero)  
- Nonparticipation in the proficiency testing event (score is zero)  
- Lack of consensus among all laboratories participating in the proficiency testing event (score is ungradable)  
These actions are documented. (See also QSA.01.01.01, EP 5)  
Note: This requirement also applies when the laboratory's cumulative score for the event meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) requirements for satisfactory performance. | |
<p>| QSA.01.02.01, EP 3 | The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented. | |
| QSA.01.02.01, EP 5 | For cytology proficiency testing, the laboratory maintains records of acceptable testing performance, or documentation of retesting and corrective action, for individuals engaged in the examination of gynecologic preparations. (See also QSA.01.01.01, EP 7) | |</p>
<table>
<thead>
<tr>
<th>QSA.01.03.01, EP 1</th>
<th>The laboratory has written policies and procedures for testing proficiency testing samples.</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA.01.03.01, EP 7</td>
<td>The laboratory staff who performed the proficiency testing along with the laboratory director sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens. <strong>Note:</strong> The laboratory director may delegate this responsibility in writing to a technical consultant meeting the qualifications of 42 CFR 493.1409 (for moderate-complexity testing) or a technical supervisor meeting the qualifications of 42 CFR 493.1447 (for high-complexity testing).</td>
</tr>
</tbody>
</table>
| QSA.01.05.01, EP 1 | The laboratory has written policies and procedures that include acceptability criteria to evaluate the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and regulated analytes for which compatible proficiency testing samples are not available. **Note:** Acceptable methods of evaluating accuracy and reliability include the following:  
  - *Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)–certified reference laboratory for comparison with its own results.*  
  - *Interlaboratory quality control results are used to evaluate the continuing accuracy and reliability of the tests not included in the proficiency testing program (for example, peer comparisons).*  
  - *Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff member who performs such testing.*  
  - *Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.* |
| QSA.01.05.01, EP 2 | The laboratory performs verification testing at least every six months. The verification is documented. |
| QSA.01.05.01, EP 3 | When performance verification is unacceptable, the laboratory performs an investigation of all potential causes, evidence of review, and corrective action sufficient to address and correct the issues identified in the investigation. These activities are documented. |
| QSA.02.01.01, EP 1 | When adding or replacing an unmodified US Food and Drug Administration (FDA)–approved test, method, or instrument, the laboratory verifies the manufacturer’s performance specifications, including the following:  
  - Accuracy  
  - Precision  
  - Reportable range  
The verification is documented. |
| QSA.02.01.01, EP 2 | When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following:
- Accuracy
- Precision
- Reportable range
- Analytic sensitivity
- Analytic specificity, including interfering substances

**Note:** Modified tests, methods, or instruments include the following:
- Test procedures with modifications to the US Food and Drug Administration (FDA)–approved use for specimen type, reagents, instrument, procedural steps, or other components
- Tests or methods developed in the laboratory with no FDA evaluation
- Tests, methods, or instruments not subject to FDA clearance |

| QSA.02.01.01, EP 3 | When replacing an old test, method, or instrument, the laboratory’s verification includes a correlation between the old and new test, method, or instrument. The correlation is documented.

**Note 1:** This element of performance also applies when reference tests are brought in-house.

**Note 2:** The laboratory has the discretion to determine the minimum number of data points and acceptable levels of correlation required for statistical validity and clinical usage of the test result. |

| QSA.02.01.01, EP 4 | For a new test, method, or instrument, the laboratory verifies that the reference intervals (normal ranges) apply to the test, method, or instrument and population served. The verification is documented. |

| QSA.02.01.01, EP 5 | The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented. |

| QSA.02.01.01, EP 6 | The laboratory’s verification includes the establishment of written quality control procedures for each testing system or methodology. |

| QSA.02.02.01, EP 1 | The laboratory has a written procedure for calibration that includes, at a minimum, the following:
- The requirements established by the instrument manufacturer
- The number of calibration levels
- The type of calibration materials used
- The concentration of the calibration materials
- The frequency of calibration
- The acceptable performance limits for the calibration |

<p>| QSA.02.02.01, EP 4 | The laboratory follows its procedure for calibration. The calibration performance is documented. |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA.02.02.01, EP 5</td>
<td>The laboratory recalibrates when indicated by evaluation of the following data: ▪ Calibration ▪ Calibration verification ▪ Quality control results ▪ Performance and function checks The recalibration is documented. (See also EC.02.04.01, EP 3; QSA.02.11.01, EPs 1–7)</td>
</tr>
<tr>
<td>QSA.02.02.01, EP 6</td>
<td>The laboratory has a written procedure for corrective action when calibration or control results fail to meet the laboratory’s criteria for acceptability. The corrective action is documented.</td>
</tr>
<tr>
<td>QSA.02.03.01, EP 1</td>
<td>The laboratory has a written procedure for calibration verification that includes the following, at a minimum: ▪ The requirements established by the instrument manufacturer ▪ The number of calibration verification levels ▪ The type of calibration verification materials used ▪ The concentration of the calibration verification materials ▪ The frequency of calibration verification ▪ The acceptable performance limits for the calibration verification</td>
</tr>
<tr>
<td>QSA.02.03.01, EP 5</td>
<td>The laboratory follows its procedure for calibration verification. The calibration verification performance is documented.</td>
</tr>
<tr>
<td>QSA.02.04.01, EP 1</td>
<td>Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A complete IQCP that consists of the following three parts that the laboratory director signs and dates prior to implementation: ▪ Risk assessment ▪ Quality control plan ▪ Quality assessment</td>
</tr>
<tr>
<td>QSA.02.04.01, EP 2</td>
<td>Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that is established by the laboratory in its own environment by its own testing personnel. <strong>Note:</strong> The risk assessment may include test, method, or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.</td>
</tr>
</tbody>
</table>
| QSA.02.04.01, EP 3 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that contains an evaluation of the following five components:  
■ Specimen  
■ Environment  
■ Reagent  
■ Test system  
■ Testing personnel |
| QSA.02.04.01, EP 4 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that encompasses the following three phases of the entire testing process:  
■ Preanalytic  
■ Analytic  
■ Postanalytic  
**Note:** The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of error. |
| QSA.02.04.01, EP 5 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that includes the manufacturer’s instructions or other information needed to assess risk in all three phases of the testing process.  
**Note:** The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers’ instructions. |
| QSA.02.04.01, EP 6 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan for devices at each location throughout a facility. |
| QSA.02.04.01, EP 7 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation. (See also LD.04.05.09, EP 2) |
| QSA.02.04.01, EP 8 | Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness. |
| QSA.02.06.01, EP 1 | A written quality control policy exists for each specialty and subspecialty offered as part of pathology and clinical laboratory services. |
| QSA.02.07.01, EP 1 | Before using control material for quality control purposes, the laboratory defines, in writing, control ranges for each lot number. |
| QSA.02.07.01, EP 2 | The laboratory determines through repetitive testing the statistical parameters for each lot number of control material, including mean, standard deviation, and coefficient of variation. The parameters are documented. |
| QSA.02.07.01, EP 5 | A manufacturer’s control range may be used if the laboratory can verify that the mean it obtained reflects the manufacturer’s mean. The verification is documented. **Note:** The laboratory may use values from package inserts only until it has established its own control ranges, or if the test is used so infrequently that calculations of valid statistics are not possible, or if a pattern of using package insert values does not exist. |
| QSA.02.07.01, EP 6 | A manufacturer’s control range may be used if the laboratory director determines, in writing, that the manufacturer’s range is narrow enough to provide results with meaningful clinical applications. |
| QSA.02.07.01, EP 7 | The laboratory establishes statistical parameters for unassayed control materials over time through concurrent testing of control materials with previously determined statistical parameters. The established statistical parameters are documented. |
| QSA.02.07.01, EP 8 | For hematology and coagulation testing: The laboratory generates statistics using the standard deviation of duplicate pairs when using patient samples as controls. The statistics are documented. **Note:** Patient controls may be used to supplement the commercial controls if an acceptable level of precision has been defined. |
| QSA.02.08.01, EP 1 | The laboratory has written policies and procedures to perform correlations between analytes when the same analytes are tested using different methodologies or instruments or at different locations. (See also QSA.01.03.01, EP 3) **Note 1:** This element of performance is not applicable when both of the following criteria are met:  
  - Testing is performed under a separate Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate.  
  - The tests are used for a separate patient population (for example, blood gas analysis for patients throughout the hospital versus scalp pH analysis for neonates).  
**Note 2:** Correlations are not required for test methods classified as waived procedures. |
| QSA.02.08.01, EP 2 | The laboratory performs correlations at least once every six months. The correlations are documented. |
| QSA.02.10.01, EP 1 | The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented. |
| QSA.02.10.01, EP 3 | The laboratory uses two quality control materials of different concentrations for each quantitative procedure on each day the procedure is performed. The quality control results are documented. |
| QSA.02.10.01, EP 4 | The laboratory uses negative and positive control material for each qualitative procedure on each day the procedure is performed. The quality control results are documented. |
| QSA.02.10.01, EP 5 | The laboratory uses a negative and graded or titered positive reactivity control material for procedures that produce graded or titered results each day the procedure is performed. The quality control results are documented. |
| QSA.02.10.01, EP 6 | The laboratory uses a negative and positive reactivity control material to test staining materials for intended reactivity each day the procedure is performed. The quality control results are documented. |
| QSA.02.10.01, EP 7 | The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each day the procedure is performed. The quality control results are documented.  
*Note: For polymer-based immunohistochemical methods, a negative control is not required.* |
| QSA.02.10.01, EP 8 | When direct antigen systems include an extraction phase, the laboratory uses two quality control materials, one of which is capable of detecting extraction errors. The quality control results are documented. |
| QSA.02.10.01, EP 9 | For each electrophoretic determination, the laboratory tests at least one quality control material containing the substances being identified or measured in patient testing. The quality control material is tested concurrent with patient specimens. The quality control result is documented. |
| QSA.02.10.01, EP 10 | For thin layer chromatography, each plate or card is spotted with a calibrator containing the substances or drug groups identified or reported by the laboratory. The calibrator includes at least one control material on each plate or card and is processed through each step of patient testing, including the extraction phase. The quality control result is documented. |
| QSA.02.10.01, EP 11 | If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented.  
*Note: Alternative quality control testing includes split sampling for testing by another method or in another laboratory or previously tested patient specimens tested in duplicate.* |
| QSA.02.10.01, EP 14 | The laboratory performs quality control testing before resuming patient testing when the following occurs:
- A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and quality control results are not adversely affected by reagent lot number changes.
- Major preventive maintenance or replacement of critical parts influences test performance.
- After calibration in order to verify that the calibration protocol was successful.
The quality control results are documented. |
| QSA.02.10.01, EP 16 | A qualified* individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment is documented.
| QSA.02.10.03, EP 1 | The laboratory analyzes positive control material to verify the performance of reagents and staining procedures for flow cytometry methods at the following frequencies:
- Each day of analysis for lymphocyte subset and CD34+ hematopoietic stem cell enumeration (single or dual platform) measurements
- At least monthly for neoplastic hematolymphoid immunophenotyping
The quality control results are documented. (See also DC.02.01.05, EP 3) |
| QSA.02.10.03, EP 2 | The laboratory selects the source of positive control material to verify the performance of reagents and staining procedures for flow cytometry methods according to the following criteria:
- External positive controls for lymphocyte subset and CD34+ hematopoietic stem cell quantitations
- External and/or internal positive controls for neoplastic hematolymphoid cell immunophenotyping
The quality control results are documented. **Note:** External positive controls are normal patient or commercial controls. (See also DC.02.01.05, EP 3) |
| QSA.02.10.03, EP 3 | The flow cytometry laboratory analyzes positive control material to verify the performance of reagents and staining procedures based on the application and method of analysis as follows:  
- Two levels of positive control for single platform measurements of CD4+ lymphocytes  
- Two levels of positive control for single platform measurements of CD34+ stem cell concentrations  
- Two levels of positive control for dual platform measurements of CD34+ stem cell concentrations  
- One level of positive control for dual platform measurements of CD4+ lymphocyte  
The quality control results are documented. (See also DC.02.01.05, EP 3) |
| QSA.02.10.03, EP 4 | The laboratory analyzes positive control material for single and dual platform flow cytometry quantitative tests at least daily or each time the flow cytometer is restarted. The quality control results are documented. (See also DC.02.01.05, EP 3) |
| QSA.02.11.01, EP 1 | The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following:  
- Patient test results  
- Work records  
- Equipment performance testing records  
- Quality control results (See also QSA.02.02.01, EP 5) |
| QSA.02.11.01, EP 3 | The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented.  
**Note:** Technical staff performing the review use specific criteria or computer algorithms to identify outlier results for manual review. Examples of criteria include the following:  
- Unacceptable quality control results  
- Test results that do not correlate with a patient’s known condition, age, sex, diagnosis, or pertinent clinical data; distribution of patient test results; and relationship with other test parameters  
- Incongruent test results on one patient  
- Abnormal test results  
- Critical values (See also LD.04.05.01, EP 1; QSA.02.02.01, EP 5) |
| QSA.02.11.01, EP 5 | The laboratory performs daily screening for errors in patient test results due to handwritten or manual data entry (for example, clerical errors). The daily screening is documented. (See also QSA.02.02.01, EP 5)  
**Note:** Screening a sample of data is acceptable for compliance with this element of performance.
| QSA.02.11.01, EP 6 | The laboratory performs screening for errors (for example, electronic transmission errors, formatting errors) in electronic and printed patient test results at a frequency defined by the laboratory. The screening is documented. *(See also QSA.02.02.01, EP 5)* |
| QSA.02.11.01, EP 7 | The laboratory performs review of other records (for example, work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented. *(See also QSA.02.02.01, EP 5)* |
| QSA.02.12.01, EP 1 | The laboratory has written policies and procedures to monitor, assess, and correct problems identified in the preanalytic, analytic, and postanalytic processes. |
| QSA.02.12.01, EP 4 | The laboratory performs corrective action when the following situations occur:
  - Quality control results do not meet the laboratory’s criteria for acceptability.
  - An instrument does not meet function check or performance testing requirements.
  - Incidents of incorrect test results are reported.
  - Patient test results are reported outside of the laboratory’s reportable range of test results.
  - Criteria for proper storage of reagents and specimens are not met.
  - Other incidents of unsatisfactory specimen collection, testing, or reporting are identified.
The corrective action is documented. |
| QSA.02.12.01, EP 5 | For each quality control result outside acceptable limits, the laboratory conducts an investigation of all potential causes, provides evidence of review, and takes corrective action. These activities are documented. |
| QSA.02.12.01, EP 7 | As part of the corrective action, the laboratory documents the following:
  - Related quality control results
  - Related repeat patient testing
  - Related correction of individual results |
| QSA.02.12.01, EP 9 | When the laboratory becomes aware of an incorrect test result, it notifies the authorized person ordering the test, and if different, the individual using the test results. The notification is documented. *(See also QSA.08.08.01, EPs 5 and 6)* |
| QSA.02.12.01, EP 10 | The laboratory issues a written corrected report to the practitioner who ordered the test or will receive the results as soon as the patient test results become available. |
| QSA.02.13.01, EP 1 | The laboratory has written policies and procedures for storing, preparing, evaluating, and tracking reagents. |
| QSA.02.13.01, EP 4 | The laboratory evaluates kits, including reagents, standards, diluents, and other ancillary reagents. The evaluation is documented. |
| QSA.02.13.01, EP 5 | The laboratory checks the following opened or prepared items for positive and negative reactivity, as well as graded reactivity, if necessary:
- Each batch of reagents prepared in-house
- Lot number and shipment of commercially prepared reagents
- Disks
- Stains
- Antisera
- Identification systems using two or more substrates or reagents, or a combination of substrates and reagents
The reactivities are documented. |
<p>| QSA.02.13.01, EP 6 | The laboratory documents the lot numbers of reagents in a manner that permits tracking when specific reagents are in use. |
| QSA.02.13.01, EP 9 | The laboratory verifies that the water used meets the criteria for the test method and does not interfere with specificity, accuracy, or precision of the test (for example, culturing deionized or distilled water, verifying pH). The verification is documented. |
| QSA.02.14.01, EP 1 | The laboratory has written policies and procedures for labeling reagents and solutions. |
| QSA.03.01.01, EP 1 | Autopsies are performed by pathologists or physicians whose credential files document their qualifications in anatomic pathology, or by qualified individuals under the direct supervision of pathologists or qualified physicians. (If the pathologist is also serving as a laboratory director, see also HR.01.02.03, EP 1, for qualifications.) |
| QSA.04.01.01, EP 2 | The laboratory uses a positive and, as appropriate, a negative control material for each qualitative procedure in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented. <strong>Note:</strong> A negative control is not required for the mycology germ tube test. |
| QSA.04.01.01, EP 3 | The laboratory uses a positive control material with graded reactivity for procedures that produce graded results in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented. |
| QSA.04.01.01, EP 4 | The laboratory performs quality controls on biochemical panels at least once prior to or concurrent with patient testing for each new batch, lot, or shipment, and at a frequency that meets the manufacturer’s instructions, if more stringent. The quality control results are documented. |</p>
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<th>Standard</th>
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<tr>
<td><strong>QSA.04.01.01, EP 5</strong></td>
<td>The laboratory performs quality controls each day the procedure is performed for deoxyribonucleic acid (DNA) probes, camp tests, and beta-lactamase methods other than the Cefinase brand method. The quality control results are documented.</td>
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| **QSA.04.01.01, EP 6** | The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened at a frequency consistent with laboratory policy or manufacturer’s instructions, if more stringent, for the following:  
  - Bacitracin  
  - Catalase  
  - Coagulase plasma  
  - The Cefinase brand method  
  - Germ tube  
  - ONPG  
  - Optochin  
  - Oxidase  
  - Spot indole  
  - X, V, and XV factor discs or strips  
  - Yeast morphology media  
The quality control results are documented.  
**Note:** If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01. |
| **QSA.04.01.01, EP 7** | The laboratory performs quality controls for typing sera when prepared or opened and every six months thereafter or at a frequency consistent with laboratory policy or the manufacturer’s instructions, if more stringent. The quality control results are documented. |
| **QSA.04.02.01, EP 1** | Prior to reporting patient results, the laboratory performs quality control testing using approved reference organisms for each lot or shipment of antibacterial, antimycobacterial, and antifungal susceptibility testing agents.* The quality control results are documented.  
<p>| <strong>QSA.04.02.01, EP 2</strong> | The laboratory performs antibacterial and antifungal susceptibility quality control testing each day the procedure is performed unless the laboratory demonstrates satisfactory performance that would qualify the laboratory to perform quality control testing on a weekly basis. (For more information on developing an individualized quality control plan, refer to Standard QSA.02.04.01.) The quality control results are documented. |
| QSA.04.02.01, EP 3 | To sustain weekly quality control testing, for each nonobvious error, the laboratory retests the out-of-control antimicrobial agent/organism combination on the day the error occurred and performs daily quality control for a total of 5 consecutive patient test days. The activities are documented. <strong>Note:</strong> If quality control is not sustained for a total of 5 days, then to requalify for weekly quality control, the laboratory documents that control strains were tested for a minimum of 20 to 30 consecutive test days for each antimicrobial agent/organism combination. No more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable range. |
| QSA.04.02.01, EP 4 | The laboratory performs antimycobacterial susceptibility quality control testing on a weekly basis, and on each new batch of media, and on each new lot number and shipment of antimycobacterial agent(s). The quality control results are documented. |
| QSA.04.03.01, EP 1 | The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. The reactivity is documented. |
| QSA.04.03.01, EP 2 | The laboratory performs quality control testing on stains at the following frequencies: With each new lot number and weekly for Gram stains. The quality control results are documented. |
| QSA.04.03.01, EP 3 | The laboratory performs quality control testing on stains at the following frequencies: Concurrent with each staining procedure for staff who do not routinely perform Gram stains (for example, staff on call). The quality control results are documented. |
| QSA.04.03.01, EP 4 | The laboratory performs quality control testing on stains at the following frequencies: Each day of use for nonfluorescent acid-fast stains and special stains (for example, spore, capsule, flagella). The quality control results are documented. |
| QSA.04.03.01, EP 5 | The laboratory performs quality control testing on stains at the following frequencies: Each time of use for fluorescent acid-fast and other fluorescent stains. The quality control results are documented. |</p>
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<th>Standard</th>
<th>Section Details</th>
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| QSA.04.04.01, EP 2 | The laboratory documents its receipt of each microbiological culture media shipment and the condition of the following:  
  - Cracks in the Petri dishes  
  - Unequal filling of plates  
  - Cracked media  
  - Hemolysis  
  - Freezing  
  - Excessive number of bubbles  
  - Contamination |
| QSA.04.04.01, EP 3 | The laboratory or the preparer performs quality control testing on new batches, lot numbers, and shipments of microbiological culture media, including sterility testing, using recommended organisms before or concurrently with the use of new batches of media.  
  **Note:** If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01. |
| QSA.04.04.01, EP 4 | The laboratory maintains documentation of microbiological culture media quality control results performed by the manufacturer if the laboratory does not retest before use. |
| QSA.04.04.01, EP 5 | The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms. The quality control results are documented. |
| QSA.04.04.01, EP 6 | The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented. |
| QSA.04.06.01, EP 1 | The laboratory has written policies and procedures to isolate and identify bacteria, mycobacteria, and fungi from potential sites of infection that address the following:  
  - Name of test(s) used  
  - Type(s) of media required  
  - Reagent(s) needed  
  - Required confirmatory testing |
| QSA.04.07.01, EP 1 | The laboratory defines the recommended volume of blood to be drawn for each blood culture. Definition is based on an approved clinical guideline,* manufacturers’ requirements, and instrument specifications.  
  *Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document M47 (Principles and Procedures for Blood Cultures). |
| QSA.04.07.01, EP 2 | The laboratory’s processing of conventional (manual) blood cultures includes visual inspection for microbial growth (turbidity, growth of microcolonies, hemolysis, color changes, gas production):
- After 12 to 24 hours of incubation at 35°C
- Twice daily for days one and two
- Daily for days three to seven
The results are documented. |
| QSA.04.07.01, EP 3 | The laboratory establishes guidelines for the collection, transport, and processing of blood cultures to minimize contamination and support infection prevention and control activities. |
| QSA.05.01.01, EP 1 | The laboratory has written policies and procedures for the blood transfusion service. |
| QSA.05.01.01, EP 4 | The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology* conducts a review of the policies and procedures of the blood transfusion service every two years. The review is documented. **Note:** A designee is not permitted to conduct this review. 
| QSA.05.01.01, EP 7 | The transfusion service obtains written documentation of approval from the medical director when clinical situations warrant an exception to policies, processes, or procedures. |
| QSA.05.01.01, EP 9 | The policies and procedures for the blood transfusion service define the staff responsible for the provision of blood, blood components, tissue, derivatives, and services. |
| QSA.05.02.01, EP 1 | The laboratory has written policies and procedures for maintaining a minimum inventory of blood and blood components. |
| QSA.05.02.01, EP 3 | A written agreement with a blood supplier includes the following:
- The responsibilities of both parties and approval by the transfusion service director or administrator
- The process for procurement, transfer, and availability of blood and blood components if the laboratory itself does not provide blood banking services on site
- The notification by the blood supplier to the laboratory’s transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV) |
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<tr>
<th>QSA code</th>
<th>EP</th>
<th>Description</th>
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<tbody>
<tr>
<td>QSA.05.02.03, EP 1</td>
<td>The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.</td>
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<tr>
<td>QSA.05.02.05, EP 1</td>
<td>The laboratory has written policies and procedures for releasing blood and blood components to the blood supplier or another organization.</td>
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<tr>
<td>QSA.05.03.01, EP 1</td>
<td>The laboratory inspects received, stored, or issued blood or blood components for evidence of hemolysis and bacterial contamination. The inspection is documented.</td>
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<tr>
<td>QSA.05.03.03, EP 1</td>
<td>The laboratory has written policies and procedures for controlling transport, storage, and return of unused blood (including reissuance of returned blood) from other parts of the organization to the blood bank.</td>
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<tr>
<td>QSA.05.04.01, EP 4</td>
<td>The laboratory records blood and blood components storage temperatures continuously or at least once every four hours. The temperatures of blood storage are documented.</td>
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<tr>
<td>QSA.05.04.03, EP 2</td>
<td>The laboratory has written policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.</td>
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<tr>
<td>QSA.05.05.01, EP 1</td>
<td>The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents.</td>
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<tr>
<td>QSA.05.05.01, EP 5</td>
<td>If IgG-coated red cells and A and B cells used for reverse grouping are prepared locally, the laboratory tests for reactivity and specificity of those cells. The reactivity results and specificity are documented.</td>
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<tr>
<td>QSA.05.06.01, EP 1</td>
<td>The laboratory has written policies and procedures for reagent reactivity testing.</td>
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<tr>
<td>QSA.05.06.01, EP 2</td>
<td>Each day the procedure is performed, and when a new lot of reagents is first used, the laboratory tests at least one vial from each lot number of antisera, reactive cells, and reagents for reactivity. The reactivity results are documented. <strong>Note:</strong> This testing includes positive and negative reactivity when recommended by the manufacturer.</td>
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<tr>
<td>QSA.05.06.01, EP 3</td>
<td>The laboratory confirms that each reagent reacts as expected. The confirmation is documented.</td>
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<tr>
<td>QSA.05.06.01, EP 4</td>
<td>The laboratory retains a copy of manufacturers’ reagent package inserts. The date placed into service is documented.</td>
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<tr>
<td>QSA.05.07.01, EP 1</td>
<td>The organization has written policies and procedures addressing specimen collection for typing and cross-matching.</td>
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| QSA.05.07.01, EP 4 | The request forms and the specimen label for typing and crossmatching include the following:  
- The recipient’s full name  
- The unique identifying number  
- The specimen collection date |
| QSA.05.08.01, EP 1 | The laboratory has written policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type. |
| QSA.05.09.01, EP 1 | The laboratory has written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood. |
| QSA.05.09.01, EP 4 | The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood for any blood products containing greater than 2 mL of red blood cells. The results are documented. |
| QSA.05.09.01, EP 5 | The laboratory compares current ABO group, Rh type, and antibody screen test results to historical results. Discrepancies are investigated and resolved prior to transfusion. The investigation is documented. |
| QSA.05.09.01, EP 9 | The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood. The results of this test are documented. |
| QSA.05.09.03, EP 8 | The laboratory validates computer systems used for ABO incompatibility testing. The activities are documented. |
| QSA.05.10.01, EP 1 | The laboratory has written policies and procedures for identifying donor blood and recipient blood. |
| QSA.05.11.01, EP 1 | The laboratory’s written policies and procedures for emergent release of blood address selection of blood and blood components when compatibility testing is incomplete. |
| QSA.05.11.01, EP 2 | The laboratory obtains documentation justifying the release of uncrossmatched blood in an emergency situation. The clinician responsible for the recipient authenticates the documentation. |
| QSA.05.13.01, EP 1 | The laboratory’s written policies and procedures for the administration of Rh immune globulin address:  
- Criteria to identify patients eligible for prophylaxis  
- Procedure to determine dose of RhIG required  
- Optimal timing of administration following exposure |
| QSA.05.14.03, EP 1 | The laboratory has written policies and procedures that address the processing of plasma components. |
| QSA.05.14.03, EP 8 | The laboratory has written policies and procedures that address the transfusion of plasma components containing a significant amount of incompatible ABO antibodies or unexpected red cell antibodies.*  
*Additional information can be found in the current editions of the AABB's Standards for Blood Banks and Transfusion Services and Technical Manual. |
| QSA.05.14.05, EP 1 | The laboratory’s written policies and procedures for irradiation of blood and blood components address the following: Validation of the target dose of radiation delivered according to the manufacturers’ recommendations and the blood or blood component. |
| QSA.05.14.05, EP 2 | The laboratory’s written policies and procedures for irradiation of blood and blood components address the following: A process to confirm that the target dose of irradiation has occurred.*  
*For additional information, see US Food and Drug Administration guidance, July 22, 1993, "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products." |
| QSA.05.14.05, EP 3 | The laboratory’s written policies and procedures for irradiation of blood and blood components address the following: Assignment of expiration date not to exceed the original expiration date or 28 days from date of irradiation, whichever is sooner. |
| QSA.05.14.05, EP 4 | The laboratory’s written policies and procedures for irradiation of blood and blood components address the following: Documentation of blood or blood component irradiation, including date and time of irradiation, unit numbers, dose of radiation, duration of radiation, and the staff performing the irradiation. |
| QSA.05.14.07, EP 1 | The laboratory’s written policies and procedures define methods to leukoreduce blood and blood components. |
| QSA.05.14.07, EP 2 | The laboratory’s written policies and procedures to leukoreduce blood and blood components address the following: Leukocyte reduction to less than $5 \times 10^6$ for apheresis platelets and red blood cells. |
| QSA.05.14.07, EP 3 | The laboratory’s written policies and procedures to leukoreduce blood and blood components address the following: Leukocyte reduction to less than $8.3 \times 10^5$ for whole blood derived platelets. |
| QSA.05.17.01, EP 1 | The laboratory has written policies and procedures for transfusion-related activities. |
| QSA.05.17.01, EP 3 | The laboratory has distinct written policies and procedures for neonatal transfusion-related activities.*  
*Additional information can be found in the current editions of the AABB’s Standards for Blood Banks and Transfusion Services and Technical Manual. |
| QSA.05.18.01, EP 1 | The organization has written policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration. |
| QSA.05.18.01, EP 4 | Patient care staff monitor the patient during blood and blood component administration to detect suspected transfusion-related adverse events. The monitoring is documented. |
| QSA.05.18.01, EP 5 | The organization provides training for staff who administer and monitor blood and blood component transfusions. The training is documented. |
| QSA.05.18.01, EP 6 | The organization assesses competency for staff who administer and monitor blood and blood component transfusions. The competency is documented. |
| QSA.05.19.01, EP 1 | The laboratory has written policies and procedures for investigating suspected transfusion-related adverse events. |
| QSA.05.19.03, EP 1 | The laboratory has written policies and procedures for investigating a suspected transfusion-related adverse event, including the protocol for a transfusion reaction workup. |
| QSA.05.19.03, EP 2 | The transfusion reaction workup protocol includes written criteria to determine if a hemolytic reaction has occurred. |
| QSA.05.19.03, EP 5 | When a suspected transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory takes corrective action to prevent recurrence. The corrective action is documented. |
| QSA.05.19.05, EP 1 | The transfusion service director interprets the evaluation of test results provided as part of the transfusion reaction workup. The interpretation is documented. |
| QSA.05.20.01, EP 2 | The laboratory has written procedures for the notification of blood recipients of potential human immunodeficiency virus (HIV) infection. |
| QSA.05.21.01, EP 2 | The laboratory has written procedures for the notification of blood recipients of potential hepatitis C (HCV) infection. |
| QSA.05.23.01, EP 1 | The laboratory's written policies and procedures for blood donation are consistent with US Food and Drug Administration (FDA) regulations.*  
*The current CFR and blood guidance from the US Food and Drug Administration (FDA) can be found at [http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm](http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm). |
| QSA.05.24.03, EP 1 | The laboratory has written policies and procedures that address blood donor collection, including handling, processing, testing, dating, labeling, storing, and distributing, according to state and federal regulation.*  
*Additional practice guidance may be found in the AABB standards or AABB Technical Manual. |
| QSA.05.24.03, EP 6 | The laboratory complies with US Food and Drug Administration (FDA) specifications for donor blood labels.  
**Note:** ISBT 128 is the preferred bar code symbology and should be used in accordance with International Council for Communality in Blood Banking Automation (ICCBBA) standards, whenever possible. |
| QSA.05.25.01, EP 1 | The laboratory’s or designated department’s written policies and procedures for therapeutic apheresis address:  
- Documentation of doctor’s orders  
- Patient informed consent process  
- Acceptance of medical responsibility for the procedure  
- Treatment of adverse reactions  
- Patient monitoring  
- Documentation of procedure |
| QSA.05.25.01, EP 2 | The laboratory or the designated department documents the following elements in the patient’s therapeutic apheresis record:  
- Patient identification  
- Diagnosis  
- Equipment serial number  
- Operator  
- Date and time of procedure start and end  
- Lot numbers of all fluids used and replaced in the device  
- Blood volume processed  
- Amount of fluid removed from patient  
- Patient assessment  
- Time out procedure prior to placing venous access device  
**Note:** Equipment serial numbers are not required for therapeutic phlebotomy performed by gravity. |
| QSA.06.01.01, EP 1 | The laboratory performs at least one level of quality control material with each clinical chemistry run of patient specimens. The quality control results for each run are documented.  
**Note:** The laboratory defines a “run” for each test system. Within each 24-hour period, the laboratory tests each level of quality control material at least once. |
| QSA.06.02.01, EP 1 | The laboratory tests at least two different levels of quality control materials for blood gas testing each day the procedure is performed. The combination of controls and calibrators used each day of testing are rotated to check normal, alkalosis, and acidosis levels. The quality control results are documented. |
| QSA.06.02.01, EP 2 | The laboratory tests at least one level of quality control material for each eight hours of patient blood gas testing. The quality control results are documented. **Note:** The laboratory should attempt to perform quality control testing as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before or after the 8-hour mark, providing a 30-minute window. Ranges in excess of +/- 30 minutes that produce a window of more than an hour do not meet the intent of this element of performance. |
| QSA.06.03.01, EP 1 | The laboratory’s written quality control and testing procedures for maternal serum marker prenatal screening include the following: Establishment of laboratory specific median values or verification of manufacturer’s median values consistent with the population served. |
| QSA.06.03.01, EP 2 | The laboratory’s written quality control and testing procedures for maternal serum marker prenatal screening include the following: Criteria and frequency for recalculation or reverification of the median values at specifically defined intervals. |
| QSA.06.03.01, EP 3 | The laboratory’s written quality control and testing procedures for maternal serum marker prenatal screening include the following: Evaluation of new reagent lots against the current median values with adjustments of the median in response to changes in median values that affect clinical interpretation. |
| QSA.06.03.03, EP 1 | The laboratory has written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP). |
| QSA.06.04.01, EP 1 | The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis. |
| QSA.06.04.01, EP 2 | The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: Extraction and use of control materials that challenge each step of the testing process. |
| QSA.06.04.01, EP 3 | The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis. |
| QSA.06.04.01, EP 4 | The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The detection and evaluation of carryover. |
| QSA.06.04.01, EP 5 | The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The frequency of monitoring column and detector performance. |
| QSA.06.04.03, EP 1 | The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis. |
| QSA.06.04.03, EP 2 | The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: Extraction and use of control materials that challenge each step of the testing process. |
| QSA.06.04.03, EP 3 | The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis. |
| QSA.06.04.03, EP 4 | The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: The detection and evaluation of carryover. |
| QSA.06.04.03, EP 5 | The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: For quantitative tests, an established reportable range and limit of detection. |
| QSA.06.04.05, EP 1 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis. |
| QSA.06.04.05, EP 2 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Extraction and use of control materials that challenge each step of the testing process. |
| QSA.06.04.05, EP 3 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Criteria and frequency for establishing mass calibration and optimum performance.  
**Note:** Some organizations refer to mass spectrometer optimum performance as being “in tune.” Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods). |
| QSA.06.04.05, EP 4 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The detection and evaluation of carryover. |
| QSA.06.04.05, EP 5 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: For quantitative tests, an established reportable range and limit of detection. |
| QSA.06.04.05, EP 6 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Establishment and validation of identification criteria for the specific technique applied (for example, liquid chromatography–mass spectrometry versus gas chromatography–mass spectrometry). **Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) documents C62 (Liquid Chromatography–Mass Spectrometry Methods) and C43 (Gas Chromatography–Mass Spectrometry Confirmation of Drugs). |
| QSA.06.04.05, EP 7 | The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Liquid chromatography–mass spectrometry includes evaluation, reduction, and monitoring of matrix effects and ion suppression. **Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods). |
| QSA.08.02.01, EP 1 | The cytology technical supervisor establishes written policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation. |
| QSA.08.03.01, EP 1 | The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services. |
| QSA.08.03.01, EP 7 | The laboratory performs reeducation and other corrective actions (for example, adjusting workload, if indicated) for significant cytology discrepancies as defined by the cytology technical supervisor. Reeducation and other corrective actions occur within a time frame that prevents recurrence. The performance is documented. |
| QSA.08.03.01, EP 8 | The laboratory annually generates an aggregated statistical report that includes the following:  
- The number of cytology cases examined  
- The number of specimens processed by specimen type  
- The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation)  
- The number of gynecologic cases with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which the histology results were available for comparison  
- The number of gynecologic cases in which cytology and available histology reports are discrepant  
- The number of gynecologic cases in which a rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm(s) |
| QSA.08.04.01, EP 1 | The laboratory has written policies and procedures that address cytology workload limits. |
| QSA.08.04.01, EP 2 | The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening. |
| QSA.08.04.01, EP 7 | Both the laboratory and the cytotechnologist maintain workload records of the total number of cytology slides examined, regardless of the site or laboratory, and the number of hours spent examining slides for each 24-hour period. |
| QSA.08.04.01, EP 8 | The cytology technical supervisor reassesses the workload limits for each staff member every six months, or more frequently as specified in the laboratory's policy. The reassessment is documented. |
| QSA.08.04.01, EP 9 | The cytology technical supervisor reestablishes, in writing, workload limits for each staff member through a documented assessment of case reviews based on each staff member's performance against the laboratory's overall statistical values. |
| QSA.08.04.01, EP 10 | The cytology technical supervisor investigates any discrepancies with the assessment of staff performance, including reasons for deviation and any corrective actions taken. The investigation is documented. |
| QSA.08.05.01, EP 1 | The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation. |
| QSA.08.06.01, EP 1 | A qualified* individual reviews a random sample of negative gynecologic slides before reporting patient results. The review is documented.  
| QSA.08.06.01, EP 4 | Records of the review of a random sample of negative gynecologic slides are available and include initial examinations and rescreening results. The results are documented. |
| QSA.08.06.03, EP 1 | The laboratory has written policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings. |
| QSA.08.07.01, EP 1 | An individual qualified as a cytology technical supervisor reviews and confirms all nongynecologic slides. This review is documented. |
| QSA.08.07.01, EP 2 | A cytology technical supervisor reviews and confirms all gynecologic slides interpreted as reactive or reparative, premalignant or malignant, or any of the following epithelial cell abnormalities:  
- Squamous cell  
- Atypical squamous cells of undetermined significance (ASC-US) or high-grade squamous intraepithelial lesion (HSIL) (ASC-H)  
- LSIL-Human papillomavirus (HPV)/mild dysplasia/ cervical intraepithelial neoplasia 1 (CIN 1)  
- HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion  
- Squamous cell carcinoma  
- Glandular cell  
- Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, glandular)  
- Atypical cells favor neoplastic (endocervical or glandular)  
- Endocervical adenocarcinoma in situ  
- Adenocarcinoma endocervical, endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS  
- Other malignant neoplasms This review is documented. (See also QSA.08.04.01, EP 3) |
<table>
<thead>
<tr>
<th>QSA.08.07.01, EP 3</th>
<th>All gynecologic and nongynecologic test reports reviewed by a cytology technical supervisor have a written or secured electronic signature.</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA.08.08.01, EP 2</td>
<td>The cytology laboratory communicates results that require urgent patient follow-up to the authorized person ordering the test and, if different, the individual responsible for using the test results. The communication is documented.</td>
</tr>
<tr>
<td>QSA.08.08.01, EP 5</td>
<td>When an incorrect cytology result is reported, a corrected report is generated and indicates the basis for the correction. (See also QSA.02.12.01, EP 9)</td>
</tr>
<tr>
<td>QSA.08.08.01, EP 6</td>
<td>When an incorrect cytology result is reported, the laboratory communicates directly with the ordering physician or other authorized individual qualified to follow up with the patient. The communication is documented. (See also QSA.02.12.01, EP 9)</td>
</tr>
</tbody>
</table>
| QSA.09.01.01, EP 1 | The laboratory has written policies and procedures for processing cytogenetic specimens that address the following:  
- The use of separate incubators equipped with independent electrical circuits or emergency power systems and emergency alarms for amniotic fluid and chorionic villus cultures  
- Duplicate or independently established cultures for each tissue type whenever possible  
- Independent harvesting of duplicate amniotic fluid and chorionic villus flasks or plates |
| QSA.09.02.01, EP 1 | The laboratory has written policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting. |
### QSA.09.03.01, EP 2

The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Determination of the number of cells to count and/or analyze and the number karyotyped based on tissue type, culture method, and clinical reason for referral as follows:

**Cells to count**
- For peripheral blood samples (non-neoplastic disorders), a minimum of 20 cells
- **Note:** When mosaicism is suspected, a minimum of 30 cells
- For amniotic fluid (in situ) samples, a minimum of 15 cells from a minimum of 15 colonies
- For non-amniotic fluid cell cultures, a minimum of 20 cells
- For chorionic villus cultured preparation samples, a minimum of 20 cells
- For solid tissue samples, a minimum of 20 cells

**Cells to analyze**
- Minimum of five cells for the following samples: amniotic fluid (in situ), cultured chorionic villus, non-neoplastic blood cells, and non-neoplastic solid tissue
- Minimum of 20 cells, whenever possible, for neoplastic studies of marrow, blood, or solid tumor specimens
- Two or more cultures, whenever possible, for neoplastic bone marrow, blood, or solid tumor specimens

**Cells to karyotype**
- Two cells karyotyped for each non-neoplastic case study, with at least one karyogram per cell line for amniotic fluid, chorionic villus, solid tissue, and peripheral blood cell specimens
- For neoplastic case studies, a minimum of two cells karyotyped, and in addition, one karyogram for each subclone, and one karyogram of a normal cell if observed for solid tumor, blood, or bone marrow specimens

### QSA.09.03.01, EP 3

The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Determination of X and Y chromatin counts based on the performance of a full chromosome analysis.

### QSA.09.03.01, EP 4

The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Level of band resolution necessary for interpretation purposes.

### QSA.09.03.01, EP 5

The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Confirmatory testing performed for atypical results.
<table>
<thead>
<tr>
<th>Standard</th>
<th>Flow Number</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA.09.03.01</td>
<td>EP 6</td>
<td>The laboratory’s written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Criteria for clinical circumstances in which an abbreviated chromosome study may be conducted.</td>
</tr>
<tr>
<td>QSA.09.03.05</td>
<td>EP 1</td>
<td>The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Validation of each probe.</td>
</tr>
<tr>
<td>QSA.09.03.05</td>
<td>EP 2</td>
<td>The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Establishment of normal cut off values for each probe.</td>
</tr>
<tr>
<td>QSA.09.03.05</td>
<td>EP 3</td>
<td>The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Use of a control consistent with hybridization assay based on signal patterns of hybridization and specimen type.</td>
</tr>
<tr>
<td>QSA.09.03.05</td>
<td>EP 5</td>
<td>The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Criteria for scoring results.</td>
</tr>
<tr>
<td>QSA.09.03.07</td>
<td>EP 1</td>
<td>The laboratory has written quality control and testing procedures for chromosomal microarray analysis.</td>
</tr>
<tr>
<td>QSA.09.03.07</td>
<td>EP 2</td>
<td>The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: probe specificity.</td>
</tr>
<tr>
<td>QSA.09.03.07</td>
<td>EP 3</td>
<td>The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: assessment of the genomic copy number.</td>
</tr>
<tr>
<td>QSA.09.03.07</td>
<td>EP 4</td>
<td>The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: assay resolution.</td>
</tr>
<tr>
<td>QSA.09.03.07</td>
<td>EP 5</td>
<td>The laboratory’s written quality control and testing procedures for chromosomal microarray analysis include the following: study limitations, including copy number variation.</td>
</tr>
<tr>
<td>QSA.09.04.01</td>
<td>EP 1</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The media used.</td>
</tr>
<tr>
<td>QSA.09.04.01</td>
<td>EP 2</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The reactions observed.</td>
</tr>
<tr>
<td>QSA.09.04.01</td>
<td>EP 3</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells counted.</td>
</tr>
<tr>
<td>QSA.09.04.01</td>
<td>EP 4</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells karyotyped.</td>
</tr>
<tr>
<td>QSA.09.04.01, EP 5</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of chromosomes counted for each metaphase spread.</td>
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<tr>
<td>QSA.09.04.01, EP 6</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The quality of the banding.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.04.01, EP 7</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The resolution, based on the clinical information provided to the laboratory for the type of tissue or specimen and the type of study required.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.04.01, EP 8</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: An adequate number of karyotypes prepared for each patient.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.04.01, EP 9</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The culture conditions.</td>
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<tr>
<td>QSA.09.04.01, EP 10</td>
<td>The laboratory documents the stages of the cytogenetic testing process and results, including the following: The incubation times.</td>
<td></td>
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<tr>
<td>QSA.09.05.01, EP 1</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: A summary and interpretation of the observations.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.05.01, EP 2</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: The number of cells counted and analyzed.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.05.01, EP 3</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: Use of the International System of Cytogenetic Nomenclature.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.05.01, EP 4</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: Documentation of any preliminary report, such as a verbal or telephone report.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.05.01, EP 5</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: All clinical information required for interpretation.</td>
<td></td>
</tr>
<tr>
<td>QSA.09.05.01, EP 6</td>
<td>The laboratory interpretive reports for cytogenetic testing include the following information: Band resolution for constitutional cases.</td>
<td></td>
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<tr>
<td>QSA.10.01.01, EP 1</td>
<td>The embryo laboratory has written procedures for each laboratory test performed.</td>
<td></td>
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<tr>
<td>QSA.10.02.01, EP 1</td>
<td>The embryo laboratory has written procedures for method validation.</td>
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<td>Section</td>
<td>Content</td>
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</table>
| QSA.10.04.01, EP 1 | The embryo laboratory documents the following for the media it uses:  
- Procedures for the quality control of culture media  
- Completion of a visual check for physical damage to the media container and evidence of media contamination before its use  
- For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities  
- The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media  
- For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement  
- Evidence that manufacturers’ specifications for using media are followed  
- Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement  
- Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotrophic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory’s written procedures |
| QSA.10.05.01, EP 1 | The embryo laboratory labels each cryopreservation container with the date the specimen was frozen and the patient’s name or unique identifier. |
| QSA.10.05.01, EP 2 | The embryo laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank. |
| QSA.10.06.01, EP 1 | If cryopreserved specimens are received or transferred to other facilities, the embryo laboratory has written policies and procedures for the receipt or transfer of cryopreserved specimens. |
| QSA.10.06.01, EP 3 | For transferred specimens, the embryo laboratory documents the following:  
- Freezing procedure used  
- Copies of patient release forms  
- Log sheets that accompany the cryopreserved specimens |
| QSA.11.01.01, EP 4 | Each individual performing manual cell counts performs one level of control for every eight hours of testing. The quality control results are documented. |
| QSA.11.01.01, EP 6 | For manual hematology tests, the laboratory defines written criteria for acceptable precision of duplicate samples. |
| QSA.11.01.01, EP 8 | For manual determination of hemoglobin, the laboratory uses two levels of control for every eight hours of patient testing. The quality control results are documented. **Note:** Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance. |
| QSA.11.02.01, EP 1 | The laboratory performs quality control testing across a range of clinically significant values on each day that it performs coagulation testing. The quality control results are documented. |
| QSA.11.02.01, EP 2 | For automated coagulation testing systems: The laboratory performs two levels of quality control material each eight hours of patient testing. The quality control results are documented. **Note:** Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance. |
| QSA.11.02.01, EP 3 | For automated coagulation testing systems: The laboratory performs two levels of quality control material each time reagents change. The quality control results are documented. |
| QSA.11.02.01, EP 6 | For manual coagulation testing systems (any coagulation test with a manual pipetting step): Each staff who performs a test analyzes two levels of quality control materials before testing individual patient samples. The quality control results are documented. |
| QSA.11.02.01, EP 7 | For manual coagulation testing systems (any coagulation test with a manual pipetting step): Each staff who performs a test analyzes two levels of quality control materials each time reagents change. The quality control results are documented. |
| QSA.11.02.01, EP 10 | The laboratory has written policies and procedures based on an approved clinical guideline* to collect specimens for the performance of plasma-based coagulation assays. *Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document H21 (Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays). |
| QSA.12.01.01, EP 1 | The laboratory has written quality control practices and validation methods for histocompatibility, including clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed human leukocyte antigen (HLA)–specific antibodies. |
| QSA.12.02.01, EP 1 | The laboratory has written criteria for crossmatching, including the following:  
- Selecting patient serum samples for crossmatching  
- The preparation of donor cells or cellular extracts (for example, solubilized antigens, nucleic acids), appropriate to the crossmatch technique(s) performed |
| QSA.12.02.01, EP 3 | The laboratory crossmatches potential recipients and donors before transplantation is performed. This crossmatching is documented.  
**Note:** For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, the laboratory has available results of final crossmatches before the kidney is transplanted. |
| QSA.12.02.01, EP 4 | The laboratory performs crossmatching with the most reactive sample collected within one month of testing. The crossmatching is documented. |
| QSA.12.02.01, EP 6 | The laboratory checks each crossmatch and compatibility test for human leukocyte antigen (HLA) Class II antigenic differences using quality control materials to monitor the test components and each phase of the test system for acceptable performance. The quality control results are documented. |
| QSA.12.02.01, EP 8 | For nonrenal transplantation, if human leukocyte antigen (HLA) testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances under which the emergency transplant was performed, if known.  
**Note:** Records of the transplant must reflect any information provided to the laboratory by the patient’s physician. |
| QSA.12.03.01, EP 1 | The laboratory has written procedures for human leukocyte antigen (HLA) serologic typing of both donor and recipient appropriate to the study or individual procedure performed, which include the following:  
- Each HLA-A, -B, -C antigen is defined by using at least two or three different sera depending on whether monospecific or multispecific sera are used.  
- Each HLA-DR antigen is defined by using five antiserum or three operationally monospecific antisera.  
- Using a technique(s) that detects HLA–specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay  
- The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed  
- The selection of typing reagents, whether prepared in-house or commercially  
- Reagents used for histocompatibility typing that are adequate to define HLA-A,-B, and-DR specificities that are officially recognized by the most recent World Health Organization (WHO) Committee on Nomenclature  
- The assignment of HLA antigens  
- Antigen redefinition and retyping  
- Using a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens |
| QSA.12.04.01, EP 1 | The laboratory has written procedures for histocompatibility testing, including the following:  
- Human leukocyte antigen (HLA) typing, antibody screening, compatibility testing, and crossmatching, to be performed for each type of cell, tissue, or organ to be transfused or transplanted  
- Testing protocols for deceased donor, living, living-related, and combined organ and tissue transplants  
- Testing protocols for patients at high risk for allograft rejection  
- The level of testing required to support clinical transplant protocols (for example, antigen or allele level) |
| QSA.12.06.01, EP 1 | The laboratory has written criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens that include the following:  
- Viability of all suspensions exceeding 80% at the start of culture  
- A demonstrated lack of cytotoxic antibodies for sera used in media  
- Each mixed lymphocytic culture test includes an autologous control and unrelated control responders and stimulators.  
- Incubating and labeling techniques discriminate between positive and negative responses. |
| QSA.12.07.01, EP 1 | The laboratory has a written policy to participate in a cell exchange program that does the following:
- Establishes valid interlaboratory reproducibility criteria
- Documents performance levels
- Takes and documents corrective action when indicated
- Maintains a cumulative record for at least two years before survey
- Provides that the director or supervisor performs and documents each review

  **Note:** The laboratory participates in at least one national or regional cell exchange program, if available, or develops an exchange system with another laboratory in order to validate interlaboratory reproducibility. |
| QSA.13.01.01, EP 3 | The pathologist and the clinical staff jointly determine and document, in writing, the categories of surgical specimens that require only a gross description and diagnosis. (See also QSA.13.04.01, EP 1) |
| QSA.13.03.01, EP 1 | The laboratory documents its receipt of surgical specimens. |
| QSA.13.03.01, EP 2 | The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage. |
| QSA.13.03.03, EP 1 | The laboratory has written policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides. |
| QSA.13.04.01, EP 3 | When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The laboratory delineates in writing the portions of the gross analysis that the individual is permitted to perform (for example, “May weigh, measure, and describe these types of tissue, but not section,” or “May only perform gross analysis of skin biopsies”). |
| QSA.13.04.01, EP 4 | When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual’s work is reviewed by the technical supervisor or a qualified pathologist within 24 hours. The review is documented. |
| QSA.13.04.01, EP 9 | Cancer pathology reports use a synoptic format.*

| QSA.13.05.01, EP 1 | The laboratory has written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope. |
| QSA.13.06.01, EP 2 | The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented. **Note:** For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. For polymer-based immunohistochemical methods, a negative control is not required. |
| QSA.13.06.01, EP 3 | Each time of use for patient testing, the laboratory performs quality controls for each type of histologic stain used. The quality control results are documented. **Note:** Documentation may be contained in a dictated report or on a separate log. |
| QSA.13.08.01, EP 1 | The histopathology laboratory has written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report. |
| QSA.13.08.01, EP 2 | The histopathology laboratory conducts an investigation and takes corrective action on disparities that exist between an initial intraoperative consultation and a report of pathology diagnosis. The disparities and corrective action are documented. |
| QSA.14.01.01, EP 1 | For immunology tests, including syphilis serology, the laboratory uses quality control materials that include a challenge of the extraction phase of the test, if applicable. The quality control results are documented. |
| QSA.14.01.01, EP 2 | The laboratory tests immunology test components for reactivity, if applicable. The reactivity results are documented. **Note:** Examples of test components that require a test for reactivity include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded controls. |
| QSA.14.01.01, EP 3 | The laboratory determines, in writing, the reactivity patterns of quality control materials for immunology tests before or concurrently with test performance, if applicable. |
| QSA.14.02.01, EP 2 | If required by the manufacturer, the laboratory tests a weak reactive quality control material for syphilis testing. The quality control result for weak reactive is documented. |
| QSA.15.01.01, EP 1 | The laboratory has written policies and procedures for molecular testing. |
| QSA.15.01.01, EP 4 | The laboratory’s policies and procedures for molecular testing address the following: Prevention of sample degradation. (See also DC.01.01.01, EP 1) |
| QSA.15.02.01, EP 3 | The laboratory performs verification studies for molecular testing. The verification studies are documented. |
| QSA.15.04.01, EP 1 | The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing. |
| QSA.15.04.01, EP 4 | For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented. |
| QSA.15.05.01, EP 1 | The laboratory reports for molecular testing include the following information: The testing methodology used. |
| QSA.15.05.01, EP 2 | The laboratory reports for molecular testing include the following information: The limitations of the method used. |
| QSA.15.05.01, EP 3 | The laboratory reports for molecular testing include the following information: Any interpretation of findings. |
| QSA.15.05.01, EP 4 | The laboratory reports for molecular testing include the following information: Any recommendations for additional testing. |
| QSA.15.05.01, EP 5 | For assays developed by the laboratory, the laboratory reports for molecular testing include a statement that the assay was developed by the laboratory. |
| QSA.15.05.01, EP 6 | The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic specific reagents (ASR). **Note:** Federal regulations require that the following disclaimer accompany the test result on the report: “This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the US Food and Drug Administration (FDA).” |
| QSA.16.01.01, EP 1 | The laboratory has written policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling. |
| QSA.16.01.01, EP 2 | The laboratory has written policies and procedures for molecular genetic testing that address the reporting of results when additional information necessary for interpreting test results is not received by the laboratory. **Note:** Additional information might be required to provide for accurate test interpretation and reporting of results. |
| QSA.16.01.01, EP 3 | The laboratory has written policies and procedures for molecular genetic testing that establish turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner). |
| QSA.16.02.01, EP 1 | The laboratory reports for molecular genetic testing include the following information: Indication for testing. |
| QSA.16.02.01, EP 2 | The laboratory reports for molecular genetic testing include the following information: List of mutant genes or alleles tested. |
| QSA.16.02.01, EP 3 | The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor. |
| QSA.16.02.01, EP 4 | The laboratory reports for molecular genetic testing include the following information: Detection rate of the test. |
| QSA.16.02.01, EP 5 | The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations. |
| QSA.16.02.01, EP 6 | The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s). |
| QSA.17.01.01, EP 1 | The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. |
| QSA.17.02.01, EP 2 | The laboratory performs quality control testing on parasitology permanent stains each month of use, or according to laboratory policy if more stringent. The quality control results are documented. |
| QSA.19.01.01, EP 1 | The laboratory has written procedures for quality control, reagent handling, and specimen handling for radiobiossay tests. **Note:** For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01. |
| QSA.19.02.01, EP 2 | For in vivo testing: The laboratory maintains records on radioactive isotopes and radiopharmaceuticals from the point of entry into the laboratory to administration and final disposal. |
| QSA.19.02.01, EP 3 | For in vivo testing: The laboratory documents in department records the following information for radioactive isotopes:  - Identity  - Date received  - Method of receipt  - Activity  - Storage  - Preparation  - Handling  - Identity of recipients  - Dates administered  - Disposal |
| QSA.20.01.01, EP 1 | The collection information for semen analysis includes the following: Method of collection. The information is documented. |
| QSA.20.01.01, EP 2 | The collection information for semen analysis includes the following: Type of specimen container. The information is documented. |
| QSA.20.01.01, EP 3 | The collection information for semen analysis includes the following: Days of abstinence. The information is documented. |
| QSA.20.01.01, EP 4 | The sample quality for semen analysis includes the following: Collection or transport problems (for example, exposure to temperatures, incomplete specimen). The information is documented. |
| QSA.20.01.01, EP 5 | The sample quality for semen analysis includes the following: Time of specimen receipt and analysis. The information is documented. |
| QSA.20.01.01, EP 6 | The sample quality for semen analysis includes the following: Abnormalities of liquefaction. The information is documented. |
| QSA.20.01.01, EP 7 | Semen analysis information includes the following, as applicable: Characteristics of semen specimens (for example, contaminants, erythrocytes, viscosity, appearance, volume, pH). The information is documented. |
| QSA.20.01.01, EP 8 | Semen analysis information includes the following, as applicable: Sperm number, motility, and progression. The information is documented. |
| QSA.20.01.01, EP 9 | Semen analysis information includes the following, as applicable: Method for sperm morphology classification, including stains, as required. The information is documented. |
| QSA.20.01.01, EP 10 | Semen analysis information includes the following, as applicable: Positive and negative controls with each assay for quantitative biochemical tests performed on the semen. The quality control results are documented. |
| QSA.20.01.01, EP 11 | Semen analysis information includes the following, as applicable: The evaluation of semen specimens based on approved clinical guidelines.* The results are documented. |

*Additional information can be found in the current editions of Clinical and Laboratory Standards Institute (CLSI) document POCT10 (Physician and Nonphysician Provider-Performed Microscopy Testing) and World Health Organization (WHO) Laboratory Manual for the Examination and Processing of Human Semen.

| QSA.21.02.01, EP 2 | The virology laboratory documents the following: Cell lines used for the virus being isolated. |
| QSA.21.02.01, EP 3 | The virology laboratory documents the following: Control checks of maintenance media. |
| QSA.21.02.01, EP 4 | The virology laboratory documents the following: Sterility checks. |
| QSA.21.02.01, EP 5 | The virology laboratory documents the following: Reagent checks for toxicity to cell lines. |
| QSA.21.02.01, EP 6 | The virology laboratory documents the following: Controls for neutralization tests. |
| QSA.21.02.01, EP 7 | The virology laboratory documents the following: Controls for hemagglutination inhibition tests. |
| QSA.21.02.01, EP 8 | The virology laboratory documents the following: Controls for immunoassays. |
| QSA.21.02.01, EP 9 | The virology laboratory documents the following: Controls for direct immunofluorescence tests. |
| QSA.21.02.01, EP 10 | The virology laboratory documents the following: Controls for indirect immunofluorescence tests. |
| QSA.21.02.01, EP 11 | The laboratory performs daily quality control for virology stains. The quality control results are documented. |
| QSA.21.04.01, EP 1 | For serodiagnostic tests for viral disease, the laboratory determines the reactivity patterns of the quality control materials before or concurrent with performance of the test and before the reporting of individual patient test results. The reactivity patterns are documented. |
| QSA.21.04.01, EP 2 | For serodiagnostic tests for viral disease, the laboratory tests components for reactivity. The reactivity patterns are documented. **Note:** Examples of such components include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded quality control materials. |
| QSA.21.04.01, EP 3 | For serodiagnostic tests for viral disease, the laboratory performs quality control testing, including internal and external controls. The quality control results are documented. |
Action Planning Tool

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Chapter Notes

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Transplant Safety (TS)

Overview
Transplantation of tissues is sometimes the only option for treatment of a wide range of diseases. In the past 10 years, advances in transplantation have led to a greater success rate for transplanted tissues. More and more people receive transplants every year. Tissue transplants are used most often to enhance the lives of recipients; they are also used at times to save lives. Tissues that are transplanted include bones, tendons, corneas, heart valves, veins, and skin. A single donor can save many lives, as well as improve the quality of life for many more.

Transplantation is not free from risk. Transmission of infections from the donor to the recipient is a significant safety concern. With the increased number of tissue transplants, the number of opportunities for transmission of infectious pathogens has also increased. Instances of tissue-borne infection in recipients of donor tissues are well documented. Diseases with documented transmission from infected donors subsequent to transplant include, to name a few, HIV, hepatitis B and C, and Creutzfeldt-Jakob disease (CJD). Recipients may also contract bacterial or fungal infections through contamination during transportation, storage, or handling. The opportunity for transmission of infectious disease will continue to increase as the number of transplants continues to rise.

Effective communication of an adverse event directly related to tissue use is critical to patient safety. The organization may become aware of an adverse event directly related to tissue use through external notification or internal detection. Prompt investigation of each adverse event provides response and treatment to recipients affected by the infected tissue and could prevent further transplantation from an infected donor.

About This Chapter
The standards in this chapter focus on the development and implementation of policies and procedures for safe tissue transplantation. The laboratory is not always responsible for the tissue program; therefore, the responsibility for compliance with these requirements would be at the organizational level.
Chapter Outline

I. Donating and Procuring Organs and Tissues—Not applicable to laboratories

II. Transplanting Organs—Not applicable to laboratories

III. Transplanting Tissues
   A. Standardized Procedures to Acquire, Receive, Store, and Issue Tissue (TS.03.01.01)
   B. Bi-directional Tracing of Tissues (TS.03.02.01)
   C. Tissue Adverse Events Investigation (TS.03.03.01)
Standards, Rationales, and Elements of Performance

Introduction to Standards TS.03.01.01, TS.03.02.01, and TS.03.03.01
The following standards apply to organizations that store or issue tissue. This includes any areas outside of the clinical laboratory that store or issue tissue; for example, surgery and outpatient centers or tissue banks. They apply to human and nonhuman cellular-based transplantable and implantable products whether classified by the US Food and Drug Administration (FDA) as a tissue or a medical device. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and are not evaluated under these standards.

Specific tissue transplant requirements apply to autologous tissue. This includes policies and procedures for identifying, tracking, storing, and handling autologous tissue, in addition to investigating tissue adverse events. Also, if the state in which an organization resides classifies something as tissue that falls outside the scope of The Joint Commission definition, the standards would apply.

Examples of Tissue and Cell Products
- Amnion/Amniotic Membrane
- Arteries
- Autologous Cells
- Autologous Tissue
- Bone
- Bone Marrow
- Bone Paste
- Bone Powder
- Bone Putty
- Cancellous Chips
- Cardiac (Heart) Valves (Aortic, Pulmonary)
- Cartilage
- Chondrocytes
- Cornea
- Demineralized Bone Matrix
- Dendritic Cells
- Dermal Matrix
- Dermis
- Dura Mater
- Embryo
- Fascia/Fascia Lata
- Hematopoietic Stem Cells
- Leukocytes
- Ligaments
- Limbal Graft
- Limbal Stem Cells
- Lymphocytes
- Marrow
- Membrane
- Meniscus
- Nerves
- Non-valved Conduits
- Oocyte/Ovarian Cells
- Ovarian Tissue
- Pancreatic Islet Cells
- Parathyroid
- Pericardium
- Peripheral Blood Stem Cells
- Progenitor Cells
- Sclera
- Semen, Sperm
- Skin
- Somatic Cells
- Tendons
- Testicular Tissue
- Therapeutic Cells (T-Cell Pheresis)/T-Cells
- Tissue (also Synthetic Tissue)
- Trachea
- Umbilical Cord Blood Stem Cells
- Vascular Graft
- Veins (Saphenous, Femoral, Iliac)
Other cellular- and tissue-based transplant or implant products whether classified by the FDA as a tissue or a medical device

Other tissues that are classified as tissues by state law and regulation

**Standard TS.03.01.01**
The organization uses standardized procedures for managing tissues.

**Elements of Performance for TS.03.01.01**

1. The organization assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuance of tissues throughout the organization.

   **Note:** Responsibility for this oversight involves coordinating efforts to provide standardized practices throughout the organization. An organization may have a centralized process (one department responsible for the ordering, receipt, storage, and issuance of tissue throughout an organization) or a decentralized process (multiple departments responsible for the ordering, receipt, storage, and issuance of tissue throughout the organization).

2. The organization develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues. *(See also TS.03.02.01, EP 5)*

3. The organization confirms that tissue suppliers are registered with the US Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.

   **Note:** This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.

5. The organization follows the tissue suppliers’ or manufacturers’ written directions for transporting, handling, storing, and using tissue.

6. The organization documents the receipt of all tissues. *(See also TS.03.02.01, EPs 3 and 6)*

* For US Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA’s online database: [http://www.fda.gov/cber/tissue/tissregdata.htm](http://www.fda.gov/cber/tissue/tissregdata.htm).
7. The organization verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented. (See also TS.03.02.01, EP 6)

**Note 1:** If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.

**Note 2:** Tissues requiring no greater control than “ambient temperature” (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt.

8. The organization maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. (See also TS.03.02.01, EP 5)

**Note 1:** Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.

**Note 2:** Tissues requiring no greater control than “ambient temperature” (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.

9. The organization continuously monitors the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues.

**Note 1:** Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.

**Note 2:** For tissue stored at room temperature, continuous temperature monitoring is not required.

10. Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency back-up plan. 

**Note:** For tissue stored at room temperature, alarm systems are not required.

11. The organization complies with state and/or federal regulations when it acts as a tissue supplier.†

† Please refer to the following website: http://www.fda.gov/cber/tissue/tisreg.htm.
**Note 1:** The US Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.

**Note 2:** Embryos, oocytes, and semen are regulated by the FDA as human cells, tissues, and cellular and tissue-based products (HCT/Ps). Organizations that manufacture HCT/Ps (recovery, processing, storage, labeling, packaging, or distribution) require FDA registration.

### Standard TS.03.02.01

The organization traces all tissues bi-directionally.

#### Elements of Performance for TS.03.02.01

1. ☑️ The organization’s records allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier. ☐

2. ☑️ The organization identifies, in writing, the materials and related instructions used to prepare or process tissues.

3. ☑️ The organization documents the dates, times, and staff involved when tissue is accepted, prepared, and issued. *(See also TS.03.01.01, EP 6)*

4. The organization documents in the recipient’s clinical record the tissue type and its unique identifier.

5. The organization retains tissue records on storage temperatures, outdated procedures, manuals, and publications for a minimum of 10 years. If required by state and/or federal laws, organizations may have to retain tissue records longer than 10 years. *(See also TS.03.01.01, EPs 2 and 8)*

6. The organization retains tissue records for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest). If required by state and/or federal laws, organizations may have to retain tissue records longer than 10 years. Records are kept on all of the following:
   - ☑️ The tissue supplier

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Please refer to 21 CFR 1271 for more information.
Note: For medical devices, the manufacturer may be the tissue supplier.

- The original numeric or alphanumeric donor and lot identification
- The name(s) of the recipient(s) or the final disposition of each tissue
- The expiration dates of all tissues

(See also TS.03.01.01, EPs 6 and 7)

7. The organization completes and returns tissue usage information cards requested by the tissue supplier.  

Standard TS.03.03.01

The organization investigates adverse events related to tissue use or donor infections.

Elements of Performance for TS.03.03.01

1. The organization has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue.

2. The organization investigates tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue.

3. As soon as the organization becomes aware of a post-transplant infection or other adverse event related to the use of tissue, it reports the infection or adverse event to the tissue supplier.

4. The organization sequesters tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection.

5. The organization identifies and informs tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus-I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue.

According to the Health Insurance Portability and Accountability Act (HIPAA) regulations regarding protected health information, “A covered entity may disclose protected health information for public health activities or other purposes to a person subject to the jurisdiction of the Food and Drug Administration (FDA) for the following purposes:

- To track products if the disclosure is made to a person required or directed by the FDA to track the product
- To enable product recalls, repairs or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems)” (Refer to 45 CFR 164.512(b)(1)(iii)(B) and (C))
Prompts to Assess Your Compliance

**Please note:** Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

Does the laboratory store or issue human and nonhuman cellular-based transplantable and implantable products classified by the US Food and Drug Administration as a tissue or a medical device? (TS.03.01.01)

**TIP:** Specific tissue transplant requirements apply to autologous tissue. Establish separate laboratory policies and procedures for identifying, tracking, storing, and handling autologous tissue, in addition to investigating adverse events.

Who is responsible for overseeing acquisition, receipt, storage, and issuance of tissues in the laboratory? (TS.03.01.01)

How does the laboratory track donors or tissue suppliers to the recipient or final dispositions? (TS.03.02.01)

How does the laboratory investigate adverse events related to tissue use and donor infections? (TS.03.03.01)
**Written Documentation Checklist**

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard. *(Note: Documentation can be on paper or in an electronic format.)*

<table>
<thead>
<tr>
<th>Transplant Safety (TS)</th>
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<tbody>
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| TS.03.01.01, EP 7 | The organization verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented. *(See also TS.03.02.01, EP 6)*  
**Note 1:** If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.  
**Note 2:** Tissues requiring no greater control than “ambient temperature” (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt. | |
| TS.03.01.01, EP 8 | The organization maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. *(See also TS.03.02.01, EP 5)*  
**Note 1:** Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.  
**Note 2:** Tissues requiring no greater control than “ambient temperature” (defined as the temperature of the immediate environment) for storage would not require temperature monitoring. | |
<p>| TS.03.02.01, EP 1 | The organization’s records allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier. | |</p>
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<th>TS.03.02.01, EP 2</th>
<th>The organization identifies, in writing, the materials and related instructions used to prepare or process tissues.</th>
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<td>TS.03.02.01, EP 3</td>
<td>The organization documents the dates, times, and staff involved when tissue is accepted, prepared, and issued. <em>(See also TS.03.01.01, EP 6)</em></td>
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Waived Testing (WT)

Overview
A laboratory test is an activity that evaluates a substance(s) removed from a human body and translates that evaluation into a result. A result can be stated as a number, presence or absence of a cell or reaction, or an interpretation. Tests that produce a result measured as a discrete number are termed “quantitative.” Tests that produce a negative or positive result, such as fecal occult blood and urine pregnancy screens, are termed “qualitative.” A test that is more precise than a qualitative test (pos/neg), but less precise than a quantitative test (numerical), is usually scored on a graded scale (1+, 2+, 3+) and is termed “semiquantitative.” Tests with analysis steps that rely on the use of an instrument to produce a result are instrument-based tests. These can be qualitative, semiquantitative, or quantitative.

Test results that are used to assess a patient’s condition or make a clinical decision about a patient are governed by the federal regulations known as the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). CLIA ’88 classifies testing into four complexity levels: high complexity, moderate complexity, provider-performed microscopy (PPM procedures, a subset of moderate complexity), and waived testing. The high, moderate, and PPM levels, otherwise called nonwaived testing, have specific and detailed requirements regarding personnel qualifications, quality assurance, quality control, and other systems. Waived testing, on the other hand, has few requirements and is less stringent than the requirements for nonwaived testing.

The Joint Commission first developed standards to address waived testing in 1992, and the standards were essentially unchanged until 2005. At that time, The Joint Commission approved revisions to its waived testing standards to address the growing number of waived testing methods, risks to patient safety and quality of care when waived testing is performed improperly, and quality problems revealed by the Centers for Medicare & Medicaid Services (CMS).

The Morbidity and Mortality Weekly Report article, “Good Laboratory Practices for Waived Testing Sites” from November 11, 2005, supports the waived testing requirements. This report indicates quality and safety concerns related to waived testing. Although by law waived tests should have insignificant risk of erroneous results, these
tests are not completely error proof, and some waived tests have potential for serious health impacts if performed incorrectly. This report draws attention to these pertinent risks:

- Lack of current manufacturers’ instructions, including manufacturers’ updates
- Failure to follow manufacturers’ instructions, including performing quality control
- Reporting of incorrect results
- Lack of adherence to expiration dates
- Inappropriate storage requirements
- Not performing test system function checks or calibration checks
- Lack of documentation, including quality control and tests performed
- Inadequate training
- Lack of understanding about good laboratory practices

These errors could cause inaccurate results that could lead to inaccurate diagnoses, inappropriate or unnecessary medical treatment, and poor patient outcomes.

Waived testing is the most common regulated testing performed by caregivers at the patient bedside or point of care. The current list of methods that are approved as waived is under constant revision, so it is advisable to check the U. S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or CMS websites, such as the following, for the most up-to-date information regarding test categorization and complete CLIA ’88 requirements:

- http://www.cms.hhs.gov/clia

### About This Chapter

When a patient performs a test on him- or herself (for example, whole blood glucose testing by a patient on his or her own meter cleared by the FDA for home use), the action is not regulated. Only testing performed by staff on patients is regulated by CLIA ’88. The Joint Commission standards apply to staff using instruments owned by staff, owned by the organization, or owned by the patient in performing waived laboratory tests. If staff members are providing only instruction or cueing the patient, then these standards do not apply. This distinction is important when caring for patients who monitor their own health care (for example, testing of glucose or prothrombin times with home devices).
Currently, The Joint Commission allows for an organization to use the patient’s results for treatment decisions. When using a patient’s results from self-testing, health care providers do not have the same types of assurance about quality as they would if they conducted the testing themselves. The following processes are not specific Joint Commission requirements but are provided only as examples of how organizations have dealt with these concerns in practice:

- Verification of competency by either confirming that the patient has been previously trained or observing the patient perform his or her first test
- Requiring the patient to perform quality control, if available for the meter, each day results are used
- Correlation of the patient’s first glucose result with testing by a main laboratory
- Confirmation of all critical and nonlinear instrument values with testing by the main laboratory
- Demonstration of proper equipment maintenance

**Note:** The Joint Commission requirements for laboratories or sites that perform nonwaived testing are located in the “Quality System Assessment for Nonwaived Testing” (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing.
Chapter Outline

I. Policies and Procedures (WT.01.01.01)
II. Identification of Staff Performing and Supervising Waived Testing (WT.02.01.01)
III. Competency of Staff Performing Waived Testing (WT.03.01.01)
IV. Performance of Quality Control Checks (WT.04.01.01)
V. Recordkeeping (WT.05.01.01)
Standards, Rationales, and Elements of Performance

Standard WT.01.01.01

Policies and procedures for waived tests are established, current, approved, and readily available.

Elements of Performance for WT.01.01.01

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate approves a consistent approach for when waived test results can be used for diagnosis and treatment and when follow-up testing is required. *(See also LD.04.01.01, EP 1)*

2. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:
   - Clinical usage and limitations of the test methodology
   - Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
   - Specimen type, collection, and identification, and required labeling
   - Specimen preservation, if applicable
   - Instrument maintenance and function checks, such as calibration
   - Storage conditions for test components
   - Reagent use, including not using a reagent after its expiration date
   - Quality control (including frequency and type) and corrective action when quality control is unacceptable
   - Test performance
   - Result reporting, including not reporting individual patient results unless quality control is acceptable
   - Equipment performance evaluation

*Note 1: Policies and procedures for waived testing are made available to testing personnel.*
Note 2: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

3. If manufacturers’ manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

4. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, or a qualified designee, approves in writing policies and procedures for waived testing at the following times:
   - Before initial use of the test for patient testing
   - Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years
   - When changes in procedures occur (for example, when manufacturers’ updates to package inserts include procedural changes or when a different manufacturer is used)

5. Current and complete policies and procedures are available for use during testing to the person performing the waived test.

6. Written policies, procedures, and manufacturers’ instructions for waived testing are followed. (See also WT.04.01.01, EPs 3–5)

   Note: Manufacturers’ recommendations and suggestions are surveyed as requirements.

Standard WT.02.01.01

The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate identifies the staff responsible for performing and supervising waived testing.

Note 1: Responsible staff may be employees of the organization, contracted staff, or employees of a contracted service.

Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.
Elements of Performance for WT.02.01.01

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing.

2. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, or a qualified designee, identifies, in writing, the staff responsible for supervising waived testing.

Standard WT.03.01.01

Staff and licensed independent practitioners performing waived tests are competent.

Elements of Performance for WT.03.01.01

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, or a qualified designee, provides orientation and training to, and assesses the competency of, staff and licensed independent practitioners who perform waived testing.

2. Staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the organization’s specific services. The orientation for waived testing is documented.

3. Staff and licensed independent practitioners who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented.

4. Staff and licensed independent practitioners who perform waived testing that requires the use of an instrument have been trained on its use and operator maintenance. The training on the use and operator maintenance of an instrument for waived testing is documented.

5. Competency for waived testing is assessed using at least two of the following methods per person per test:
   - Performance of a test on a blind specimen
   - Periodic observation of routine work by the supervisor or qualified designee
   - Monitoring of each user’s quality control performance
   - Use of a written test specific to the test assessed
6. Competence for waived testing is assessed according to organization policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented.

**Note 1:** When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within his or her specialty, the organization may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that he or she is authorized to perform. At the discretion of the person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate or according to organization policy, more stringent competency requirements may be implemented.

**Note 2:** Provider-performed microscopy (PPM) procedures are not waived tests. (See also HR.01.06.01, EP 18 for PPM Competency Requirements)

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**Standard WT.04.01.01**

The organization performs quality control checks for waived testing on each procedure.

**Note:** Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.

**Elements of Performance for WT.04.01.01**

1. The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate approves a written quality control plan for waived testing that specifies the method(s) for controlling procedures for quality, establishes timetables, and explains the rationale for choice of procedures and timetables. (See also LD.04.01.01, EP 1)

2. The documented quality control rationale for waived testing is based on the following:
   - How the test is used
   - Reagent stability
   - Manufacturers’ recommendations
   - The organization’s experience with the test
   - Currently accepted guidelines
3. For non-instrument-based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined by the organization’s policies. *(See also WT.01.01.01, EP 6)*

**Note:** If these elements are not defined by the manufacturer, the organization defines the frequency and number of levels for quality control.

4. For instrument-based waived testing, quality control checks are performed on each instrument used for patient testing per manufacturers’ instructions. *(See also WT.01.01.01, EP 6)*

5. For instrument-based waived testing, quality control checks require two levels of control, if commercially available. *(See also WT.01.01.01, EP 6)*

**Standard WT.05.01.01**

The organization maintains records for waived testing.

**Elements of Performance for WT.05.01.01**

1. © Quality control results, including internal and external controls for waived testing, are documented.

   **Note 1:** Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.

   **Note 2:** Quality control results may be located in the clinical record.

2. Test results for waived testing are documented in the patient’s clinical record.

3. Quantitative test result reports in the patient’s clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. *(See also DC.02.03.01, EP 14)*

   **Note 1:** Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance.

   **Note 2:** If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the patient’s permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the patient’s clinical record.

4. Individual test results for waived testing are associated with quality control results and instrument records.
Note: A formal log is not required, but a functional audit trail is maintained that allows retrieval of individual test results and their association with quality control and instrument records.

5. Quality control result records, test result records, and instrument records for waived testing are retained for at least two years.
Prompts to Assess Your Compliance

Please note: Tips do not represent new accreditation requirements. They are intended to provide helpful strategies for standards compliance.

Who is the staff member responsible for oversight of waived testing? Does his or her name appear on the CLIA certificate? (WT.02.01.01)

TIP: Assign someone to be responsible for the CLIA certificate.
- The certificate should be posted in a secure location, where it can be seen by both staff and surveyors.
- Keep track of the expiration date, and apply for renewal in a timely manner.
- If the person named on the certificate leaves the organization, someone else must be appointed and his or her name must be added to the certificate.

When was the last time waived testing procedures were updated? Are all waived testing procedures signed by the responsible staff? (WT.01.01.01)

TIP: Establish procedures for implementing a new test or changes to a test. Establish a time frame for periodic review of the manufacturer’s package inserts for each waived testing equipment and document each review for procedural updates.

How does the organization assess competencies for waived testing personnel? (WT.03.01.01)
### TIP: Competency Requirements

<table>
<thead>
<tr>
<th>Joint Commission Requirement</th>
<th>Nonwaived Testing including PPMP</th>
<th>Waived Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td>Use 6 methods (if applicable)</td>
<td>Use 2 of 4 methods</td>
</tr>
<tr>
<td></td>
<td>1. Blind testing</td>
<td>1. Blind testing</td>
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<tr>
<td></td>
<td>2. Direct observation of routine testing</td>
<td>2. Direct observation of routine testing</td>
</tr>
<tr>
<td></td>
<td>3. Monitoring of quality control performance by each user</td>
<td>3. Monitoring of quality control performance by each user</td>
</tr>
<tr>
<td></td>
<td>4. Problem-solving skills</td>
<td>4. Written test</td>
</tr>
<tr>
<td></td>
<td>5. Direct observation of instrument checks</td>
<td></td>
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<td></td>
<td>6. Monitoring result reporting</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Training and Annual Assessment</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Semiannual in the first year</td>
<td></td>
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</tbody>
</table>

| Signatures                              | Both the director/supervisor/consultant and the employee must sign that the individual has received training and is competent prior to performing testing independently. | No signature is required, but the director/designee must assess competency. |

Is each staff member and independent practitioner who performs waived testing trained for each test they are authorized to perform? (WT.03.01.01)

**TIP:** Use credentialing and privileging processes for noninstrumented waived tests. Have two years documentation of competency assessment available during survey.
Are quality control checks on each waived testing instrument used for patient or resident testing performed with two levels of controls (or less with IQCP) when available? (WT.04.01.01)

Does the waived testing documentation incorporate reference ranges? How are reference ranges for each specific waived testing established? (WT.05.01.01)

**TIP:** Train staff on the difference and purpose of internal and external quality control. Make quality control (internal and external) and lot numbers a mandatory entry.
# Written Documentation Checklist

This worksheet lists elements of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard.  

*(Note: Documentation can be on paper or in an electronic format.)*

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## Waived Testing (WT)

<table>
<thead>
<tr>
<th>√</th>
<th>Standard and EP</th>
<th>Required Written Documentation</th>
<th>Date Last Verified</th>
</tr>
</thead>
</table>
|   | WT.01.01.01, EP 2 | The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:  
  - Clinical usage and limitations of the test methodology  
  - Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)  
  - Specimen type, collection, and identification, and required labeling  
  - Specimen preservation, if applicable  
  - Instrument maintenance and function checks, such as calibration  
  - Storage conditions for test components  
  - Reagent use, including not using a reagent after its expiration date  
  - Quality control (including frequency and type) and corrective action when quality control is unacceptable  
  - Test performance  
  - Result reporting, including not reporting individual patient results unless quality control is acceptable  
  - Equipment performance evaluation  

  *(Note: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.)* | | |

|   | WT.01.01.01, EP 3 | If manufacturers’ manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument). | |
| WT.01.01.01, EP 4 | The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) certificate, or a qualified designee, approves in writing policies and procedures for waived testing at the following times:
- Before initial use of the test for patient testing
- Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years
- When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used) |
| WT.02.01.01, EP 1 | The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing. |
| WT.02.01.01, EP 2 | The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) certificate, or a qualified designee, identifies, in writing, the staff responsible for supervising waived testing. |
| WT.03.01.01, EP 2 | Staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the organization’s specific services. The orientation for waived testing is documented. |
| WT.03.01.01, EP 3 | Staff and licensed independent practitioners who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented. |
| WT.03.01.01, EP 4 | Staff and licensed independent practitioners who perform waived testing that requires the use of an instrument have been trained on its use and operator maintenance. The training on the use and operator maintenance of an instrument for waived testing is documented. |
| WT.03.01.01, EP 6 | Competence for waived testing is assessed according to organization policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented. |
**WT –16**  

| WT.04.01.01, EP 1 | **Note 1:** When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within his or her specialty, the organization may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that he or she is authorized to perform. At the discretion of the person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to organization policy, more stringent competency requirements may be implemented.  
**Note 2:** Provider-performed microscopy (PPM) procedures are not waived tests. (See also HR.01.06.01, EP 18 for PPM Competency Requirements) |
| WT.05.01.01, EP 1 | Quality control results, including internal and external controls for waived testing, are documented.  
**Note 1:** Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.  
**Note 2:** Quality control results may be located in the clinical record. |
Action Planning Tool

Use this form to track noncompliant elements of performance (EPs) and your action steps for bringing them into compliance.

<table>
<thead>
<tr>
<th>Standard and EP</th>
<th>Observation/Issue</th>
<th>Action Step</th>
<th>Individual Responsible</th>
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<tbody>
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</table>
Chapter Notes

Use this page to take notes about ideas for meeting the standards in this chapter, your laboratory’s policies and procedures that address requirements in this chapter, or the data or clinical record numbers used to determine compliance or noncompliance for EPs. If a standard is found not compliant, it can be helpful to know which data were used so they can be easily accessed when developing action plans for compliance.
The Accreditation Process (ACC)

Notices
The Joint Commission Connect™ extranet site is the primary means of communication by The Joint Commission. Any required notices to be given to an organization shall be sent to the organization via the organization’s secure Joint Commission Connect extranet site.

ACC Chapter Contents
This chapter introduces the Joint Commission’s accreditation process, beginning with general information about eligibility for accreditation and the application process, accreditation policies, and types of surveys. Details are then provided on what organizations can expect before, during, after, and between accreditation surveys. Finally, the chapter ends by listing the accreditation decision rules and outlining review and appeal procedures. This outline provides a way to easily navigate the chapter and find information quickly.
Public Information Policy .......................................................... ACC–15
Process for Responding to a Complaint ........................................... ACC–22
Early Survey Policy .......................................................................... ACC–23

Before the Survey ............................................................................... ACC–26
An Organization’s Secure Joint Commission Connect™ Site .......... ACC–26
Role of the Account Executive ......................................................... ACC–27
Electronic Application for Accreditation (E-App) ......................... ACC–27
Accreditation Contract and Business Associate Agreement ........ ACC–29
Annual and Survey Fees ................................................................. ACC–29

During the Survey ............................................................................. ACC–30
Survey Notification ........................................................................... ACC–31
Initial and Full Survey Team Composition ....................................... ACC–34
Survey Agenda .................................................................................. ACC–34
Tracer Methodology .......................................................................... ACC–37
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Notifying The Joint Commission About Organization Changes .... ACC–59
Accreditation Status of Organizations That Cease Services After a Disaster .......................................................... ACC–61
Accreditation Status of Organizations That Cease Services or Do Not Have Patients for a Period of Time ................. ACC–63
Reentering the Accreditation Process ............................................. ACC–63
Additional Surveys ........................................................................... ACC–64
Overview
The policies, procedures, and explanations of process described in this chapter apply to any health care organization interested in Joint Commission accreditation, whether it is applying for the first time or seeking continued accreditation. All laboratories must follow the policies and procedures listed in this chapter to participate in the accreditation process. Failure to follow the policies and procedures described in this chapter can result in denial of accreditation. Because this information is reviewed and revised as necessary on a continuous basis, all accredited laboratories are responsible for keeping track of changes to these policies and procedures.

Changes made to accreditation requirements between manual updates can be viewed at “The Joint Commission Requirements” page on The Joint Commission website at http://www.jointcommission.org/standards_information/tjc_requirements.aspx.

The “Accreditation Participation Requirements” (APR) chapter also includes specific requirements for accreditation participation. The APRs are existing policies and are currently effective for accreditation purposes. Cross-references to the APRs are noted in the applicable sections of this chapter.

General Eligibility Requirements
Any laboratory may apply for Joint Commission accreditation if all the following requirements are met:

- The laboratory is in the United States or its territories or, if outside the United States, is owned or operated by the US government or under a charter of the US Congress.
- If required by law, the laboratory has a facility license, CLIA license, or registration to conduct its scope of services.
The laboratory can demonstrate that it continually assesses and improves the quality of its care, treatment, and/or services. This process includes a review by clinicians or qualified designee as defined by CLIA, including those knowledgeable in the type of care, treatment, and/or services provided at the laboratory.

The laboratory identifies the services it provides, indicating which care, treatment, and/or services it provides directly, under contract, or through some other arrangement.

The laboratory provides services that can be evaluated by The Joint Commission’s standards.

Scope of Accreditation Surveys

The Joint Commission evaluates all health care services provided by the organization for which The Joint Commission has standards and makes an accreditation decision for each accreditation program surveyed. The survey results are documented by the surveyor(s) and left on site (with the exception of for-cause surveys) in the preliminary Summary of Survey Findings Report. During a survey, an organization must be prepared to provide evidence of its compliance with each applicable standard. To attain accreditation, an organization must demonstrate compliance with the standards and their elements of performance (EPs).

In addition to using standards and EPs, The Joint Commission also surveys organizations by using APRs and the Joint Commission National Patient Safety Goals (see the APR and “National Patient Safety Goals” [NPSG] chapters, respectively). Used in conjunction with the standards, these requirements help assess an organization’s performance.

Accreditation Policies

This section provides information on the policies that govern the accreditation process for laboratories and describes how The Joint Commission shares information about an individual organization.

Tailored Survey Policy

The public expects all of the programs or services delivered under the auspices of an accredited organization to have been evaluated. As such, The Joint Commission applies its Tailored Survey Policy to components (for which there are applicable Joint
Commission standards) that are organizationally and functionally integrated with the health care organization applying for accreditation (see the “Organizational and Functional Integration” section).

The Joint Commission will include another service, program, or related entity (that is, component), whether providing programs or services directly or through a contractual arrangement*, in the survey of the applicant organization under the following circumstances:

- There are Joint Commission accreditation/certification requirements applicable to the component.
- There is organizational and functional integration between the component and the applicant organization.

The Joint Commission survey, assuming satisfactory compliance, provides one accreditation award for each accreditation program surveyed (for example, ambulatory physical health care, behavioral health care, home care, nursing care centers, and so forth).

Any service, program, or related entity that is a component of an accreditation-eligible organization may independently seek accreditation if it can meet Joint Commission survey eligibility requirements. The results of such a separate accreditation survey will not affect the overall organization’s decision. If the service, program, or related entity seeks separate accreditation, the Tailored Survey Policy does not require the larger complex organization to be separately accredited.†

Complex Organization Survey Process
The complex organization survey‡ process is applied to organizations that are governed by the Tailored Survey Policy. The Joint Commission conducts a complex organization survey based on the services or programs provided by the organization, as reported in its electronic application for accreditation (E-App). After completing its E-App, the organization is able to view which manuals are applicable to the accreditation survey on the “Applicable Manuals” tab. Because a complex organization survey process involves standards in more than one of the accreditation manuals, The Joint Commission

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*Contractual arrangements are evaluated for tailoring applicability on a case-by-case basis.
†The laboratory must meet the requirements of decision rule FOC01 for the organization to be successfully accredited. See the “One-Month Survey” section in the “Accreditation Decision Rules” for the full requirement.
‡A complex organization refers to an organization that is surveyed under more than one accreditation manual.
provides the organization with access to the electronic editions of the manuals to be used in the survey before it is conducted. The Joint Commission surveys and, assuming satisfactory compliance, provides one accreditation award for each program surveyed.

**Organizational and Functional Integration**

Organizational and functional integration refers to the degree to which a component is overseen and managed by the applicant organization that is either seeking accreditation or currently accredited. A *component* is a service, program, or related entity that delivers care, treatment, or services and is eligible for survey under one of The Joint Commission’s accreditation programs listed in the INTRO chapter.

*Organizational integration* exists when an applicant organization’s governing body either directly or ultimately controls budgetary and resource allocation decisions for the component or, where individual corporate entities are involved, there is greater than 50% common governing board membership for the applicant organization and on the board of the component.

*Functional integration* exists when the entity meets at least three of the following eight criteria:

1. The applicant organization and the component do the following:
   - Use the same process for determining membership of licensed independent practitioners in practitioner panels or medical or professional staff and/or
   - Use the same process for credentialing and assigning of privileges or clinical responsibilities to licensed independent practitioners and/or
   - Share a common organized medical or professional staff between the applicant organization and the component

2. The applicant organization’s human resources function hires and assigns staff at the component and has the authority to do the following:
   - Terminate staff at the component
   - Transfer or rotate staff between the applicant organization and the component
   - Conduct performance appraisals of the staff who work in the component

3. The applicant organization’s policies and procedures are applicable to the component, with few or no exceptions.

4. The applicant organization manages significant operations of the component (that is, the component has little or no management authority or autonomy independent of the applicant organization).
5. The component’s clinical records are integrated into the applicant organization’s clinical record system.
6. The applicant organization applies its performance improvement program to the component and has authority to implement actions intended to improve performance at the component.
7. The applicant organization bills for services provided by the component under the name of the applicant organization.
8. The applicant organization and/or the component portrays to the public that the component is part of the organization through the use of common names or logos; references on letterheads, brochures, telephone book listings, or websites; or representations in other published materials.

A checklist to help determine whether organizational and functional integration exists is provided in Figure 1.
# Checklist to Determine Organizational and Functional Integration

<table>
<thead>
<tr>
<th>Organizational Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Budgetary decisions</strong>—Does the governing body of the applicant organization control budget and resource allocation for component?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2. Shared governance</strong>—If separate corporate entities, do the applicant organization and the component share over 50% of governing body membership?</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Functional Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Common medical staff</strong>—Is there a unified process for credentialing staff and/or licensed independent practitioner membership?</td>
<td></td>
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<tr>
<td><strong>2. Human resources</strong>—Does the applicant organization have hiring/firing/performance appraisal authority over the component’s staff?</td>
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<tr>
<td><strong>3. Policies and procedures</strong>—Are there common policies and procedures?</td>
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<tr>
<td><strong>4. Management</strong>—Does the applicant organization manage operations of the component?</td>
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<td><strong>5. Patient records</strong>—Is there an integrated patient record system?</td>
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<tr>
<td><strong>6. Performance improvement</strong>—Is there an integrated performance improvement program? Does the applicant organization have authority to implement performance improvement actions at component?</td>
<td></td>
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<tr>
<td><strong>7. Billing</strong>—Are the component’s services billed by the applicant organization?</td>
<td></td>
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<tr>
<td><strong>8. Public portrayal</strong>—Is there public portrayal of component as part of a parent organization through names, logos, or such?</td>
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</tbody>
</table>

**Note:** Applicant organization needs minimum of one “Yes” response for organizational integration and three “Yes” responses for functional integration to include components as “sites” on the electronic application for accreditation (E-App).

**Figure 1.** Checklist to determine organizational and functional integration.
Multiorganization Option
The Joint Commission offers a multiorganization system that owns or leases at least two organizations the option of using a modified survey process. This option has the following three components:
1. A corporate orientation held at the beginning of the year
2. Surveys of participating organizations with the same survey team leader
3. A corporate summation after the last organization in the system is surveyed

The orientation session provides an opportunity for corporate staff to orient the surveyor or survey team to the structure and practices of the system. The surveyor or survey team also surveys centralized corporate services, documentation, and policies and procedures applicable to Joint Commission requirements. The corporate summation provides an overall analysis of the system’s strengths and weaknesses. It also provides consultation and education related to accreditation survey findings across the system.

Through the multiorganization option, The Joint Commission accredits the individual health care organizations that are part of a multiorganization system, not the system itself. Therefore, each organization within a system receives its own accreditation decision and Accreditation Survey Findings Report. The findings and decision for one organization within a system have no bearing on those of another organization within the system.

Concurrent Survey Option
The Joint Commission offers a concurrent survey option for laboratories or systems with multiple Joint Commission–accredited laboratories. This option provides a structure across the entire system and has the following components:
- Unannounced surveys of participating laboratories occur at the same time.
- Each participating laboratory must demonstrate compliance with all Joint Commission requirements independent of any other laboratories within the system.
- Each participating laboratory under a separate health care organization identification number will receive a separate survey report and accreditation decision.

The concurrent survey process works best when conducted in systems where 12 or fewer entities wish to be surveyed at the same time.
Contracted Services

The Joint Commission evaluates an organization’s management and oversight of the quality of care, treatment, and services (for which there are Joint Commission standards) provided under contractual arrangements. The Joint Commission reserves the right to evaluate, as part of its survey, the care, treatment, and services provided by another organization or provider on behalf of the applicant organization. It may survey performance issues between the contracted organization and the applicant organization, regardless of the accreditation decision of the contracted organization. The Joint Commission also surveys care, treatment, and services provided on site under contract to the applicant organization.

Proficiency Testing Monitoring

The Joint Commission and the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) require you to maintain successful performance on proficiency testing (PT) (see “Quality System Assessment for Nonwaived Testing” [QSA] Standard QSA.01.01.01, EP 5, Note 1). The Joint Commission receives unsuccessful PT performance data from CMS and the PT providers for all regulated analytes through an electronic communication link. Unsuccessful PT performance is defined as a failure to achieve satisfactory performance for two consecutive or two out of three consecutive testing events.

When an unsuccessful PT event occurs, a letter will be posted to the organization’s secure Joint Commission Connect™ extranet site to request a Plan of Action (POA). Laboratories will be asked to submit information including, but not limited to, the following:

- Current and historical PT reports
- Analysis and corrective action of the unacceptable PT results
- Steps taken to assure the accuracy and reliability of patient results
- Review and approval of the corrective action by the laboratory director named on the CLIA ’88 certificate (see “Leadership” [LD] Standard LD.04.01.01, EP 1, Note 2)

If the problem cannot be resolved, an on-site evaluation may be conducted which may ultimately affect your accreditation status. An on-site evaluation may also be conducted for extreme problems or those that jeopardize patient safety. At any time during the process, the laboratory may voluntarily discontinue testing. If the laboratory decides to voluntarily discontinue testing, the laboratory must notify the project manager at The Joint Commission in writing. The laboratory may not resume testing until reinstatement.
criteria are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing. Reinstatement criteria include, but are not limited to, evidence of satisfactory performance on two PT events.

If the POA is acceptable, a letter will be posted to the organization’s secure Joint Commission Connect site. PT monitoring will continue. The laboratory will be required to submit copies of the next two consecutive PT events.

If the laboratory fails to achieve satisfactory performance on one of the next two events, the laboratory must cease testing for a minimum of six months after the notice is issued for the testing specified. The laboratory may not resume testing until reinstatement criteria are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

A full description of the requirements for accreditation may be found in the “Accreditation Participation Requirements” (APR) chapter at APR.10.03.01. For questions or notifications regarding unsuccessful PT and submission of a corrective POA, please contact the Laboratory Project Manager by phone at 630-792-5248, via e-mail at estawczyk@jointcommission.org, or in writing at The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181, ATTN: Laboratory Project Manager.

**Initial Surveys**

An organization that is seeking Joint Commission accreditation for the first time or that has not been denied accreditation by The Joint Commission during the previous four months is eligible for an initial survey if it serves the required minimum number of patients regardless of how long the organization has been in operation. The full scope of applicable standards is reviewed during the survey. The Joint Commission’s policy for assessing and monitoring organizations new to the accreditation process is as follows:

- Laboratories new to the accreditation process must be able to demonstrate a four-month track record of compliance with the standards at the time of the initial survey.
- If an organization new to the accreditation process demonstrates compliance with applicable Joint Commission accreditation requirements, the organization will receive accreditation.
The accreditation effective date for an organization that undergoes an initial survey is the date on which an acceptable ESC was submitted, if the organization has a Requirement for Improvement (RFI). If there are no RFIs, the effective date is the day after the last day of the survey.

**Survey Postponement Policy**

In rare circumstances, it may be appropriate to request a survey postponement. An organization should direct a request for a postponement to its account executive. A request to postpone a survey may be granted if a major unforeseen event has occurred that has totally or substantially disrupted operations, such as the following:

- A natural disaster or major disruption of service due to a facility failure
- The organization’s involvement in an employment strike
- The organization’s cessation of admitting or treating patients
- The organization’s inability to treat and care for patients and its transfer of patients to other facilities or organizations

The Joint Commission may, at its discretion, approve a request to postpone a survey for an organization not meeting any of the criteria described above. The organization may be charged a fee to defray costs.

**Information Accuracy and Truthfulness Policy**

The accuracy and veracity of relevant information, whether actually used in the accreditation or certification processes, are essential to the integrity of the Joint Commission’s accreditation and certification processes. *Falsification*, as the term is used in the Joint Commission’s Information Accuracy and Truthfulness Policy, applies to both commissions and omissions in sharing information with The Joint Commission. Information provided at any time by the organization must be accurate and truthful (see APR.01.02.01 in the APR chapter). Such information may be furnished in any of the following manners:

- Provided verbally or in writing
- Obtained through direct observation or interview by Joint Commission surveyor(s) or reviewer(s)
- Derived from documents supplied by the organization to The Joint Commission, including, but not limited to, an organization’s comprehensive systematic analysis (for example, a root cause analysis) in response to a sentinel event or an organization’s request for accreditation/certification
Electronically transmitted data or documents including, but not limited to, data or documents provided as part of the E-App process

An attestation that the organization does not currently and knowingly use Joint Commission full-time, part-time, or intermittent surveyors or reviewers to provide any accreditation-/certification-related consulting services including, but not limited to, the following:
- Helping an organization meet Joint Commission accreditation/certification requirements
- Helping an organization with any intracycle monitoring process
- Conducting mock surveys for an organization
- Helping an organization in the ESC process

**Policy Requirements**
The Joint Commission’s Information Accuracy and Truthfulness Policy includes the following:

1. An organization must never provide The Joint Commission with falsified (as defined below) information relevant to the accreditation/certification process. The Joint Commission construes any effort to do so as a violation of the organization’s obligation to engage in the accreditation/certification process in good faith.

2. *Falsification* is defined for this policy as the fabrication, in whole or in part, and through commission or omission, of any information provided by an applicant or accredited organization/certified program to The Joint Commission. This includes, but is not limited to, any redrafting, reformatting, or content deletion of documents.

3. The organization may submit additional material that summarizes or otherwise explains original information submitted to The Joint Commission. These materials must be properly identified, dated, and accompanied by the original documents.

4. The Joint Commission conducts an evaluation when it has cause to believe that an accredited organization/certified program may have provided falsified information to The Joint Commission relevant to the accreditation/certification process. Except as otherwise authorized by the president of The Joint Commission, the evaluation may include an unannounced on-site survey. This survey uses special protocols designed to address the information determined by The Joint Commission to constitute possible falsification. It assesses the degree of actual organization compliance with the standards and EPs that are the subject of the allegation, if appropriate.

5. The Joint Commission takes action to deny accreditation/certification to an organization/program whenever The Joint Commission is reasonably persuaded that the organization/program has provided falsified information.
6. The Joint Commission may notify responsible federal and state government agencies of any organization/program subject to such action.

7. If an organization/program is denied accreditation/certification because it provided falsified information, The Joint Commission prohibits it from participating in the accreditation or certification process for a period of one year. The president of The Joint Commission, for good cause only as determined in his/her sole discretion, may waive all or a portion of this waiting period. If an organization requests to participate in the accreditation/certification process prior to the completion of the one-year prohibition period and the president of The Joint Commission does honor the request, executive leadership will be so notified.

**Good Faith Participation in Accreditation/Certification**

The Joint Commission requires each organization seeking (re)accreditation or (re)certification to engage in the process in good faith. The Joint Commission may deny accreditation or certification to any organization that fails to participate in the process in good faith. The following are examples of actions interfering with good faith participation:

- **Deceiving The Joint Commission.** Compliance with the Information Accuracy and Truthfulness Policy requires a commitment on the part of the accredited organization/certified program not to deceive The Joint Commission in any aspect of the accreditation/certification process, such as during the completion of an application for accreditation/certification, during the Intracycle Monitoring (ICM) process, or during a survey/review.

- **Deceiving the public.** An accredited organization/certified program is not acting in good faith if it misleads the public about the meaning and limitations of accreditation/certification. Also, an accredited organization/certified program must not inaccurately suggest to the public that its accreditation/certification award applies to any unaccredited affiliated or otherwise related activities.

- **Retaliation.** The Joint Commission invites open communication from any accredited organization’s/certified program’s staff and recipients of care, treatment, and services about any standards compliance or other issues related to the accreditation/certification process. An organization’s/program’s good faith participation in the accreditation/certification process is questioned if the organization/program does any of the following:
The Accreditation Process

- Attempts to discourage such communication—for example, by taking disciplinary steps against an employee solely because that employee provides information to The Joint Commission
- Threatens those who communicate with The Joint Commission with a defamation lawsuit based solely on what was said to The Joint Commission
- Allows the treatment or access to services of any individual or staff member to be adversely affected by his or her or a family member’s communication with The Joint Commission

Standards compliance. If an organization’s/program’s conduct reflects a lack of commitment to standards compliance, issues of good faith may be raised. For example, an intentional refusal to attempt to comply with a standard could suggest a cavalier view of the accreditation/certification process.

The good faith participation requirement applies continuously throughout the accreditation/certification process.

Public Information Policy

Introduction
The Joint Commission is committed to making relevant and accurate information about health care organizations available to interested parties. Information regarding a health care organization’s quality and safety can help organizations improve their services. This information may also help educate consumers and health care purchasers in making informed choices about health care. At the same time, it is important that confidentiality of certain information be maintained to encourage candor in the accreditation and certification processes. The Joint Commission’s primary vehicle for providing public information are Quality Check® and Quality Reports.

Quality Check. Quality Check is The Joint Commission’s website for making available descriptive and performance information about accredited organizations and certified programs.

Quality Reports. The Quality Reports located on Quality Check are publicly available and include relevant and useful information about the quality and safety of care provided in individual Joint Commission–accredited organizations and –certified programs.

This policy meets the requirements of the Health Insurance Portability and Accountability Act of 1996.
Quality Reports are created at the organization level and contain information reflecting an organization’s accreditation and/or certification status, its compliance with National Patient Safety Goals, and performance measurement results, as appropriate.

**Publicly Available Accreditation and Certification Information**

Joint Commission Quality Reports for each accredited organization and/or certified program include the following information:

- The date of an organization’s/program’s most recent full on-site survey/review, and if the organization/program has had any subsequent surveys/reviews since its last full survey/review
- The accreditation/certification decision based on the most recent full on-site survey/review, as well as any subsequent updates to the decision
  - Organizations that are successful in obtaining accreditation following an initial survey will be posted on the Quality Check website.
  - Programs that achieve certification will be posted on the Quality Check website.
- For organizations in the accreditation renewal process, with an accreditation decision of Preliminary Denial of Accreditation or Denial of Accreditation, the standards with Requirements for Improvement leading to the decision
- Services included within the scope of the organization’s accreditation and/or certification decision
- A list of an organization’s previous accreditation and/or program’s certification decisions and the effective date of those decisions for the past seven (7) years
  - If the organization had a previous decision of Preliminary Denial of Accreditation, the standards with Requirements for Improvement
- The receipt of national quality recognition awards, as recognized by the Board of Commissioners
- Compliance with National Patient Safety Goal requirements

Each accredited organization/certified program is afforded the opportunity to prepare a commentary of up to two pages regarding its Quality Report. The commentary will accompany any organization/program Quality Reports distributed by The Joint Commission, whether via hard copy or The Joint Commission’s website.

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Denial of Accreditation decisions, for organizations that were in the accreditation renewal process, will be posted on the Quality Check website for a duration of one year from the rendering of the accreditation decision.
When performance measurement data is included in Quality Reports, such data will be accompanied by information regarding its source or derivation; accuracy, reliability, and validity; and appropriate uses of the data.

An organization’s Quality Report may be obtained via the Customer Service Department or through Quality Check. See “The Joint Commission Quality Report” (QR) chapter of this manual for more details.

**Release of Aggregate Data**
The Joint Commission reserves the right to publish or release aggregate data. Protected health information will not be made publicly available. Performance data displayed on Quality Check are available to any interested party at no cost and may be downloaded electronically in a series of predefined report formats through a linked webpage called “Quality Data.”

**Information That Is Publicly Disclosed on Request**

**Release of Accreditation and Certification Information.** In addition to information provided in Quality Reports, the following information may be obtained by writing or calling The Joint Commission:

- For organizations that were previously denied accreditation, are no longer certified, or withdrew from the accreditation/certification process:
  - The organization’s accreditation and/or certification history
  - Standards for which The Joint Commission had no or insufficient evidence of resolution when an organization withdrew from accreditation and was subsequently denied accreditation

**Sentinel Event Information.** As applicable, confirmation of the occurrence of a sentinel event at an accredited organization for the three-year period prior to the date of the request and The Joint Commission’s intent to apply its Sentinel Event Policy or other applicable procedures to this occurrence.

**Release of Aggregate Complaint-Related Information.** The Joint Commission addresses all incidents that pertain to alleged patient safety or quality of care issues within the scope of Joint Commission standards. Information about complaints may be forwarded by the Centers for Medicare & Medicaid Services (CMS) or other federal or state agencies having oversight responsibilities for health care organizations, federal or state legislators or legislative committees on behalf of constituents, or may be received directly from patients, families, payers, or health care professionals. As used here, the term complaint refers to an alleged adverse event, unsafe condition, or concern.
**complaint** includes potentially relevant reports that are received from federal or state agencies, identified in the media, or otherwise obtained by The Joint Commission. The Joint Commission will only disclose patient-identifiable information if authorized by the patient, as consistent with its business associate obligations, or otherwise authorized by law. For any party other than the authorizing complainant, The Joint Commission will not disclose patient name or identifiable information, per the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Upon request from any party, The Joint Commission releases the following aggregate information relating to complaints about an accredited organization or a certified program for the three-year period prior to receipt of the request: When an unannounced or unscheduled survey/review is based on information derived from a complaint or public sources, a summary of the standards areas for which Requirements for Improvement were issued as a result of The Joint Commission’s evaluation activities.

**Release of Specific Complaint-Related Information**

The Joint Commission also provides the following information as appropriate to complainants regarding their complaints (and those authorized by the complainant), or other individuals who have knowledge regarding a specific complaint:

- Confirmation of the receipt of the complaint and that it will be reviewed to determine what, if any, Joint Commission action is warranted
- Any determination that the complaint is not related to Joint Commission requirements
- If The Joint Commission has decided not to take action regarding an organization’s accreditation/a program’s certification decision, the complainant is to be so advised.
- If the complaint is related to Joint Commission requirements, upon completion of review, the course of action that was taken regarding the complaint, including the standards areas that were evaluated
- If The Joint Commission has decided not to take action regarding an organization’s accreditation/a program’s certification decision as a result of the complaint review, the complainant is to be so advised.
- If The Joint Commission has taken action regarding an organization’s accreditation/a program’s certification decision as a result of an on-site complaint review, the noncompliant standards leading to that decision will be made publicly available on Quality Check.

The term *standard area* refers to the focus area of the complaint review as it relates to The Joint Commission’s standards. Depending on the review status or outcome of the complaint review, the level of information provided may vary.
Data Release to Government Agencies and Organizations with Which The Joint Commission Performs Coordinated Survey Activities ††

The Joint Commission makes available to federal, state, local, or other governmental certification or licensing agencies or public health agencies, or any other appropriate enforcement agency, specific accreditation-related information under the following circumstances:

- When The Joint Commission identifies a serious situation in an organization that may jeopardize the health or safety of patients or the public and immediately takes action to deny accreditation
- When The Joint Commission identifies a serious situation, or a significant pattern of risk in an organization that may have jeopardized the health or safety of previous patients or the public, or that represents risk that extends beyond the organization, such as an incident involving the reuse of contaminated instruments
- If the health care organization or other individual reports the issue to the appropriate authorities, The Joint Commission will evaluate whether it, too, should report the issue.

Additional information is made available when an organization is certified for participation in a federal or state program or licensed to operate by a state agency on the basis of its accreditation. In addition, The Joint Commission may make available information to organizations with which The Joint Commission performs coordinated survey activities. The Joint Commission may advise the organization’s chief executive officer and will provide timely notice to local, state, and federal authorities having jurisdiction. The information available to government agencies and organizations with which The Joint Commission performs coordinated survey activities includes the following:

†† Section 92, PL 96-499, the Omnibus Budget Reconciliation Act of 1980, requires that Medicare providers include, in all their contracts for services costing $10,000 or more in any 12-month period, a clause allowing the Secretary of the US Department of Health and Human Services (DHHS), the US Comptroller General, or their representatives to examine the contract and the contractor’s books and records. The Joint Commission herein stipulates that if its charges to any such organization amount to $10,000 or more in any 12-month period, the contract or any agreement on which such charges are based and any of the Joint Commission’s books, documents, and records that may be necessary to verify the extent and nature of Joint Commission costs will be available to the Secretary of DHHS, the Comptroller General, or any of their duly authorized representatives for four years after the survey. The same conditions will apply to any subcontracts The Joint Commission has with related organizations if the payments under such contracts amount to $10,000 or more in any 12-month period.
Notification of official decision to render Accreditation with Follow-up Survey, Preliminary Denial of Accreditation, or Denial of Accreditation, including the rationale for the decision

Complaint information requested by CMS in accordance with The Joint Commission’s deeming authority, including the content of the complaint submitted to The Joint Commission

Complaint information, including the content of the complaint submitted to The Joint Commission, is shared with:
- CMS in accordance with The Joint Commission’s deeming authority
- A state regulatory agency that has entered into a written information-sharing agreement
- An organization with which The Joint Commission conducts coordinated survey activities

Upon request from CMS, the following information is shared:
- All final Requirements for Improvement
- A statement, if any, from the organization regarding its views on the validity of Joint Commission survey findings
- A copy of the corrective action submitted by the organization
- The results of any follow-up survey, if warranted

For governmental agencies, notification of upcoming full surveys and retrospective dates of other surveys conducted, such as random unannounced or for-cause surveys, only if the governmental agency enters into an information-sharing agreement with The Joint Commission and agrees to maintain the confidentiality of the survey dates.

A copy of the Official Accreditation Decision Report and decision letter
- For CMS upon request respecting deemed status determinations
- For state agencies that have entered into specific information-sharing agreements that permit provider-authorized release of such reports to the state agency
- Upon request from state agencies that are acting on behalf of CMS as contractors

The Joint Commission will report to CMS or the Office of the Inspector General, as appropriate, in the event that there is credible evidence of potential identification of fraud and abuse, or other criminal or civil law violation and upon notice to the health care organization.
Data Release to Cooperative Accrediting Bodies

The Joint Commission makes available to accrediting bodies with which it has formal cooperative agreements relevant portions of Official Accreditation Decision Reports and complaint-related information pertinent to the accrediting activities of the cooperative partner. Judgments as to pertinence are made solely by The Joint Commission. (For a list of organizations with which The Joint Commission has cooperative agreements, see http://www.jointcommission.org/facts_about_the_cooperative_accreditation_initiative/.)

Data Release as a Result to CLIA Requirement at 42 CFR 493.557(a)(14)

The Joint Commission agrees to disclose any laboratory’s PT results upon reasonable request by any person in accordance with Joint Commission requirements that the PT program must make available information about its program, grading methods, or other explanatory information to The Joint Commission or to any person requesting such information about a Joint Commission participant laboratory pursuant to 42 CFR 493.553(a)(6).

Joint Commission Right to Clarify

The Joint Commission reserves the right to clarify information, even if the information involved would otherwise be considered confidential, when an organization disseminates inaccurate information regarding its accreditation/certification.

Confidential Information

The Joint Commission keeps information received or developed during the accreditation/certification process confidential, such as:

- The Official Accreditation Decision Report, unless its submission is required by a governmental agency (see “Data Release to Government Agencies and Organizations with Which The Joint Commission Performs Coordinated Survey Activities”), is required by organizations with which The Joint Commission performs coordinating surveys, or is requested by an accredited body with which The Joint Commission has a formal agreement (see “Data Release to Cooperative Accrediting Bodies”)
- Information learned from the organization before, during, or following the accreditation survey, which is used to determine compliance with specific accreditation standards
- An organization’s comprehensive systematic analysis and related documents prepared in response to a sentinel event or in response to other circumstances specified by The Joint Commission
- All other materials that may contribute to the accreditation/certification decision
- Written staff analyses and executive leadership minutes and agenda materials
- Any data from an organization’s participation in the intracycle monitoring process and related corrective action plan
- The identity of any individual who files a complaint about an accredited organization, except when the complaint is shared by The Joint Commission with a governmental entity, an organization with which The Joint Commission performs coordinated surveys, or accrediting organizations with which The Joint Commission has formal complaint-sharing agreements and the receiving organization has agreed to maintain the confidentiality of the complainant. In instances when the receiving organization cannot assure the confidentiality of the complainant, any complainant-identifying information shall be redacted by The Joint Commission prior to sharing.

This policy applies to all organizations with an accreditation and/or certification history, subject to any requirements of any applicable laws.

**Process for Responding to a Complaint**

The Joint Commission’s Office of Quality and Patient Safety (OQPS) triages and reviews complaints, concerns, and inquiries related to accredited health care organizations, as received from a variety of sources. These complaints may be submitted by patients, families, and health care providers; by state and federal agencies in the form of reports; or through information from the media. The term *complaint* therefore covers a broad spectrum of information received by the OQPS.

Upon Joint Commission review of a complaint, a number of actions may result. These include recording the information for trending purposes and possible action in the future, obtaining the involved health care organization’s response to the complaint, and/or conducting an immediate for-cause survey. If The Joint Commission determines that the organization should respond to the complaint, the organization will be so notified. The request for a response will be e-mailed to the organization’s CEO and posted to the organization’s *Joint Commission Connect™* extranet site (a secure, password-protected website intended only for Joint Commission–accredited or –certified organizations and key stakeholders). The organization’s response to the complaint also takes place through its extranet site.

The complaint information posted on the *Joint Commission Connect* site may be either of the following:
- The complaint itself, if the complainant has given permission to do so
A summary of the complaint, if the complainant requested anonymity

If an accredited organization is required to respond to the complaint, it is usually required to do so within 30 business days of being notified. For more serious issues, the organization may be required to respond to the complaint within 7 business days of being notified, or sooner. When a response in a short time frame is required, the organization will be so notified.

Once a response is received, it is evaluated for compliance with the Joint Commission’s standards, National Patient Safety Goals, and APRs, as applicable. If additional information is required, the organization will be notified.

When the organization’s response is complete and has been accepted, a letter indicating acceptance is e-mailed to the CEO, and the case is considered closed.

Early Survey Policy
An organization seeking Joint Commission accreditation for the first time may choose the Early Survey Policy option. An organization surveyed under the Early Survey Policy will have two surveys. Sidebar 1 lists key features of the Early Survey Policy.

Sidebar 1. Early Survey Policy

First Survey
- Conducted for laboratories that have been in operation (licensed) at least one month; track record achievement is not required
- Licensed (according to law and regulation) or in licensing process
- Building identified, constructed, and equipped
- CEO or administrator, director of clinical or medical services (medical director), and nurse executive identified
- Identified opening date
- Announced
- Limited set of standards (physical plant, policies and procedures)
- Outcome: Limited, Temporary Accreditation

Second Survey

continued on next page
Sidebar 1. (continued)

- Ready date for survey selected by the organization within six months of the first survey
- Announced
- Full initial survey
- Outcome: Change in Limited, Temporary Accreditation decision to Accredited or Denial of Accreditation. The effective date of the accreditation decision is the day after the second survey if the organization does not receive any Requirements for Improvement (RFIs). If the organization receives at least one RFI and therefore must submit an ESC that resolves all RFIs, the effective date of the accreditation decision is the date the successful ESC is submitted. If at six months the organization is not ready for the second survey, the organization’s Limited, Temporary Accreditation decision will expire.

**Note:** Limited, Temporary Accreditation may be required for state licensure. In addition, some states require new laboratories to undergo an initial survey prior to initiating patient testing.

Eligibility for Limited, Temporary Accreditation

The Early Survey Policy is available to any organization that is currently not accredited—except for those that have been denied accreditation. An organization must declare during the application process that it wishes to be surveyed under this policy.

The First Survey. When an organization chooses to be surveyed under the Early Survey Policy, The Joint Commission conducts two on-site surveys. The Joint Commission can conduct the first survey as early as two months before the organization begins its operations, provided that the organization meets the following criteria:

- It is licensed (according to law and regulation) or in the licensing process.
- The building in which the services will be offered or from which the services will be coordinated is identified, constructed, and equipped to support such services.
- It has identified its CEO or administrator, its director of clinical or medical services, and its nurse executive, if applicable.
- It has identified the date it will begin operations.

Generally, the first survey uses a limited set of standards and assesses only the organization’s physical facilities, policies and procedures, plans, and related structural considerations.
**Limited, Temporary Accreditation Decision.** The Joint Commission grants Limited, Temporary Accreditation to an organization that is in satisfactory compliance with the limited set of standards and EPs assessed in the first of the two surveys conducted under the Early Survey Policy (see the “Early Survey Policy Option” [ESP] chapter for a list of these requirements). Since a Limited, Temporary Accreditation decision does not reflect an organization’s compliance with the full set of Joint Commission standards, the organization cannot use the Joint Commission’s Gold Seal of Approval®. An organization that is not in satisfactory compliance must reapply and begin the accreditation process again.

The Limited, Temporary Accreditation decision includes assignment of an additional announced survey against the full set of applicable standards within six months of the first survey. The survey assesses the organization’s compliance with all applicable EPs.

For organizations surveyed under the Early Survey Policy: If an organization does not receive any RFIs during the first survey, the effective date for its Limited, Temporary Accreditation decision is the day after the survey is conducted. If the organization receives at least one RFI during the first survey and therefore must submit an acceptable ESC report that resolves all RFIs, the effective date for Limited, Temporary Accreditation is the date of the acceptable ESC submission.

The Limited, Temporary Accreditation decision remains in effect until the organization has completed the second of the two surveys (which is a full survey) conducted under the Early Survey Policy or until The Joint Commission has withdrawn the Limited, Temporary Accreditation. The Joint Commission may withdraw Limited, Temporary Accreditation in the following situations:

- If an organization that was not providing services at the time of the first survey does not begin providing services when expected
- If an organization does not meet the survey eligibility criteria
- If an organization fails to accept the second survey
- If an organization is found to be not in satisfactory compliance with the applicable standards and their EPs

In any of these cases, the organization must begin the accreditation process again.
The Second Survey. The second survey under the Early Survey Policy is an announced, full, initial accreditation survey. The Joint Commission conducts this survey within six months after the first survey. If at six months the organization is not ready for the second survey, the organization’s Limited, Temporary Accreditation decision will be removed and the organization will not be accredited.

Based on survey results, the organization’s accreditation decision then changes to one of the following:
- Accredited
- Denial of Accreditation

See “Decision Categories for Organizations Seeking Accreditation Renewal” for descriptions of accreditation decisions.

The effective date of the accreditation decision is the day after the second survey if the organization does not receive any RFIs. If the organization receives at least one RFI and therefore must submit an acceptable ESC report that resolves all RFIs, the effective date is then retroactive to the date of the acceptable ESC submission. The organization’s accreditation cycle begins the day after the second survey was conducted, unless The Joint Commission reached a decision to deny accreditation.

Before the Survey
This section provides information on the steps leading to a full accreditation survey. These steps include the application process, the role of an account executive, and the Focused Standards Assessment (FSA) process.

An Organization’s Secure Joint Commission Connect™ Site
A key feature of The Joint Commission’s accreditation process is use of technology. The use of technology better enables The Joint Commission and accredited organizations to communicate accreditation-related information in a more efficient and timely manner.

The Joint Commission provides each organization with a secure, password-protected website on The Joint Commission’s extranet site for accredited organizations, Joint Commission Connect. Joint Commission Connect is the primary means of communication between The Joint Commission and accredited organizations. Full access to this site can only be granted through the use of the organization’s password. This site permits an
The Accreditation Process

organization to complete its E-App and FSA electronically. In addition, shortly after an organization’s survey, the organization’s Accreditation Survey Findings Report and its ESC report are posted on the organization’s secure site. (See the “Stimulate Improvement” section in the INTRO chapter for more details about what is available on Joint Commission Connect.)

While full access to Joint Commission Connect can only be granted via an organization’s password, employees with an e-mail address from their Joint Commission–accredited health care organization can register themselves for guest access. Guest access enables viewers to see the Leading Practice Library and Standards BoosterPaks™. Guest access does not include entry to any organization-specific data or reports.

Role of the Account Executive
The Joint Commission assigns an account executive to an organization after receiving its E-App and nonrefundable deposit. This person serves as the primary contact between the organization and The Joint Commission. He or she coordinates survey planning and handles policies, procedures, accreditation issues or services, and inquiries throughout the accreditation cycle. An applicant organization can find contact information for its account executive on its Joint Commission Connect site or by calling 630-792-3007.

Electronic Application for Accreditation (E-App)
When an organization notifies The Joint Commission that it wants to become accredited, The Joint Commission provides the organization with information explaining how to access the E-App on the organization’s secure Joint Commission Connect extranet site. (An applicant should contact Business Development at 630-792-5248 for initial access to Joint Commission Connect.) Initial applications are valid for one year. An organization needs to complete and submit its E-App upon initial application for survey and will be asked to verify the information annually. An organization can provide updates to the E-App at any time. (See the “Changes Affecting E-App Information” section for more information on notifying The Joint Commission of significant changes within an organization.)

The application provides essential information about the organization, including ownership, demographics, and types and volume of services provided. The E-App does the following:
Describes the organization seeking accreditation in terms of size and scope of services

Requires the organization to make available to The Joint Commission all official records and reports of public or publicly recognized licensing (for example, state licenses), examining, reviewing, or planning bodies during the initial on-site survey (see APR.05.01.01 in the APR chapter)

Authorizes The Joint Commission to obtain any records and reports not possessed by the organization

When accepted, establishes the terms of the relationship between the organization and The Joint Commission

Identifies an organization’s applicable standards based on programs/services provided

Drives the anticipated number of survey days, number and type of surveyors, and survey agenda activities (see the “Survey Agenda” section)

**Accuracy of the Application Information**

The Joint Commission schedules surveys based on information provided in an organization’s E-App. With the information provided, The Joint Commission determines the number of days required for a survey and the number and type of surveyors. Inaccurate or incomplete information in the E-App may necessitate an additional survey, which could delay the processing of survey findings and rendering of an accreditation decision. It may also cause the organization to incur additional survey charges.

**Forfeiture of Survey Deposit**

A nonrefundable, nontransferable deposit toward accreditation fees is required for initial customers. The Joint Commission applies the deposit to the organization’s open invoices until the deposit is exhausted. An organization scheduled for an initial survey forfeits its deposit if its survey is not conducted within one year of submitting its application. The organization must then reapply and submit a new deposit to begin the accreditation process again. **Note:** If it receives approval from The Joint Commission to postpone an initial survey (less than 20 days prior to a scheduled initial survey), the organization will be charged a fee to defray costs.

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‡‡The Joint Commission does not charge a deposit for accredited health care organizations that are seeking a new tailored (or certification) program. Also, in instances where an “owner” of multiple health care organizations has at least five accredited entities in good standing, that entity will be eligible for a deposit waiver.
Accreditation Contract and Business Associate Agreement

Organizations seeking Joint Commission accreditation for the first time or reaccreditation with The Joint Commission must submit one signed accreditation contract and a signed Business Associate Agreement. The contract outlines the responsibilities of both the organization and The Joint Commission relative to the accreditation process. This contract is separate from the E-App.

In accordance with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, and modified by the HITECH (Health Information Technology for Economic and Clinical Health) provisions of the American Recovery and Reinvestment Act of 2009, a health care organization and The Joint Commission must have a signed Business Associate Agreement before the organization’s survey can begin. This Business Associate Agreement outlines the access, use, and disclosure of any patient-protected health information between The Joint Commission and the health care organization.

An organization will not be scheduled for survey until it signs an accreditation contract and Business Associate Agreement. When this happens, The Joint Commission will proceed with the organization’s survey plans unless the organization notifies The Joint Commission in writing of its intent to withdraw from accreditation and terminate the accreditation contract. Notification in writing is necessary to terminate the accreditation contract, cease survey scheduling, and avoid a final decision of Denial of Accreditation. If an organization fails to notify The Joint Commission in writing of its intent to withdraw from accreditation and terminate its accreditation contract before a survey, The Joint Commission’s decision rules provide for a final decision of Denial of Accreditation.

Annual and Survey Fees

The Joint Commission uses a subscription billing system for all accreditation programs. Fees are determined annually and are based on the need to secure sufficient resources to cover the costs of operation. The Joint Commission generally bases individual organization annual fees on the volume and type of services provided and the sites to be included in the organization’s accreditation survey. Questions about all fees can be directed to the Pricing Unit (pricingunit@jointcommission.org) or by calling 630-792-5115.
The Joint Commission’s fee structure includes a nonrefundable, nontransferable annual fee, which recognizes the provision of substantial accreditation-related services on a continuous basis between on-site surveys. The annual fees, billed each January, are determined by the organization’s size and complexity. The annual fee for organizations applying for accreditation for the first time will be prorated, based on the quarter in which the application is submitted.

In addition to annual fees, organizations are also billed an on-site fee within two days after the survey has been conducted. The on-site fee is designed to cover the direct costs of performing a survey.

Organizations requiring additional surveys, such as to evaluate a patient safety event, will be assessed a separate survey fee.

Electronic invoices will be posted to the organization’s secure Joint Commission Connect site and are due upon receipt. The Joint Commission accepts payment for all fees in any of the following ways:

- Electronic payment using Visa, MasterCard (credit or debit), American Express, Discover, or e-check by logging on the organization’s Joint Commission Connect accreditation home page and clicking on the “What’s Due” tab or by calling Accounts Receivable staff at 630-792-5662
- Check or money order by mail to PO Box 92775, Chicago, IL 60675-2775, or overnight to One Renaissance Boulevard, Oakbrook Terrace, IL 60181
- Wire transfer by calling Accounts Receivable staff at 630-792-5662

Failure to provide timely payment of any Joint Commission fees may result in the loss of accreditation. Letters of nonpayment are posted to the health care organization’s Joint Commission Connect extranet site. Failure to pay overdue amounts will result in a loss of accreditation with no opportunity for appeal or reinstatement. For help in making a payment, please contact Accounts Receivable staff at 630-792-5662.

During the Survey
During an accreditation survey, The Joint Commission evaluates an organization’s performance of functions and processes aimed at continuously improving patient outcomes. The survey process focuses on assessing performance of important patient-centered and organization functions that support the safety and quality of care,
treatment, and services. This assessment is accomplished through evaluating an organization’s compliance with the applicable requirements in this manual, based on the following activities and information:

- Tracing the care, treatment, and services delivered to patients
- Verbal and written information provided to The Joint Commission
- On-site observations and interviews by Joint Commission surveyors
- Review of documents provided by the organization

Under this accreditation process, the full survey is the on-site evaluation piece of a continuous process. The accreditation process encourages organizations to embed the requirements into routine operations to achieve and maintain excellent operational systems on an ongoing basis. Initiatives such as the annual FSA facilitate this and also help identify and manage risk.

A survey is designed to be individualized to each organization, to be consistent, and to support the organization’s efforts to improve performance. The Joint Commission determines the length of a survey based on information supplied in the E-App that describes the organization’s size and scope of services. In addition, Joint Commission surveyors may conduct some survey activities during early morning, evening, night, and weekend hours, as necessary. These “off-shift” visits do not occur before the opening conference at the start of the survey.

Survey Notification

The Joint Commission generally conducts unannounced surveys between 18 and 24 months after a laboratory’s previous full survey, except for situations in which it would not be logical or feasible to conduct an unannounced survey. Table 1 outlines specific exceptions to unannounced surveys and the length of advance notice.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Exception</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial surveys</td>
<td>Announced</td>
<td></td>
</tr>
<tr>
<td>Early Survey Policy—1st and 2nd surveys</td>
<td>Announced</td>
<td></td>
</tr>
</tbody>
</table>

continued on next page

55 In this table, 7 days refers to 7 business days.
Table 1. (continued)

<table>
<thead>
<tr>
<th>Organizations undergoing ICM Option 2 and Option 3 surveys</th>
<th>Announced (unless the organization requests the survey to be unannounced)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Defense facilities</td>
<td>7-day notice</td>
</tr>
<tr>
<td>“Small” organizations</td>
<td>7-day notice</td>
</tr>
<tr>
<td>IIVF laboratories (freestanding)</td>
<td>7-day notice</td>
</tr>
<tr>
<td></td>
<td>Fewer than 25,000 tests per year</td>
</tr>
</tbody>
</table>

With an unannounced survey, an accredited organization will receive no notice of its survey date prior to the start of the survey. In concert with the unannounced survey process, the following procedures will be implemented:

- Accredited organizations will be able to identify, in their 15-month E-App, up to 10 days in their survey eligibility range (between 18 and 24 months after their last full survey) in which an unannounced survey should be avoided. Once the 15-month E-App has been submitted, these dates cannot be modified. These 10 days should not include federal holidays but may include regional events during which it may be difficult to conduct a survey. The Joint Commission will make every effort to accommodate the organization regarding avoiding these 10 days. However, The Joint Commission reserves the right to conduct a survey during an “avoid period.”

- An organization is required to demonstrate how it communicates on an ongoing basis to its public that if members of the public have any quality-of-care or safety concerns, they should notify The Joint Commission (see APR.09.01.01 in the APR chapter).

- If an organization knows of a surveyor who works or has worked at the organization or a competing organization or has had personal experience with the survey or that represents a potential conflict, the organization is asked to identify the individual(s) in its E-App or notify The Joint Commission via phone or e-mail as soon as possible so that another surveyor may be assigned.

Organizations are notified of upcoming Joint Commission surveys according to which of the following three types of survey they are going to receive:

1. **Unannounced Events.** On the day of the unannounced survey, by 7:30 A.M. in the organization’s local time zone (for organizations within the United States and its territories), The Joint Commission will post on the organization’s secure Joint Commission Connect site the letter of introduction, the survey agenda, and the biography and picture of each surveyor assigned to conduct the event. Once the notification—
which serves as the official notice of the upcoming event—has been posted, an e-mail notification will be sent to the individuals listed as chief executive officer, primary accreditation/certification contact, and corporate contact (if applicable) on the organization’s extranet. This e-mail will advise that an event has been scheduled for that day and instruct the contact(s) to log in to the *Joint Commission Connect* site to view the event details.

2. **Announced Events.** Thirty days prior to the scheduled announced event, The Joint Commission will post on the organization’s secure *Joint Commission Connect* extranet site the letter of introduction, the survey agenda, and the biography and picture of each surveyor assigned to conduct the event. Once this notification—which serves as the official notice of the upcoming event—has been posted, an e-mail notification will be sent to the individuals listed as chief executive officer and primary accreditation/certification contact on the organization’s extranet. This e-mail will advise that an event has been scheduled and instruct the contact(s) to log in to the *Joint Commission Connect* site to view the event details. The organization will also receive a separate e-mail by 7:30 A.M. in the organization’s local time zone (for organizations within the United States and its territories) on the morning of the event with the same information listed above.

3. **Short-Notice Events.** Seven business days prior to the scheduled event, The Joint Commission will post on the organization’s secure *Joint Commission Connect* site the letter of introduction, the survey agenda, and the biography and picture of each surveyor assigned to conduct the event. (This information is also posted on the extranet the day of survey.) Once the notification—which serves as the official notice of the upcoming event—has been posted, an e-mail notification will be sent to the individuals listed as chief executive officer and primary accreditation/certification contact on the organization’s extranet. This e-mail will advise that an event has been scheduled and instruct the contact(s) to log in to the *Joint Commission Connect* site to view the event details. The organization will also receive a separate e-mail by 7:30 A.M. in the organization’s local time zone (for organizations within the United States and its territories) on the morning of the event with the same information listed above. **Organizations that are eligible for short notice will no longer receive a phone call from a Joint Commission representative notifying them that the event has been scheduled.**


Initial and Full Survey Team Composition

Based on the size and complexity of the organization being surveyed, an accreditation survey may be conducted by one surveyor or a team of surveyors. The composition of an organization’s survey team is based on the information provided in its E-App.

On surveys with more than one surveyor, one of the surveyors is designated as the team leader. The team leader is responsible for integration, coordination, and communication of on-site survey activities. In addition to being one of the surveyors conducting the survey, the team leader serves as the primary point of on-site contact between the organization and The Joint Commission. Among other responsibilities, the team leader leads the opening conference and the daily and exit briefings.

Pathologist Specialist Option

A laboratory may choose to include a pathologist in the survey team that conducts the laboratory’s accreditation survey. This option is available at an additional cost. Please contact the Pricing Unit for the actual cost for your laboratory. The pathologist surveyor provides enhanced expertise and consultation during the survey of performance improvement activities, laboratory directorship activities, and cytology and histology activities.

Lab Advantage Option

A laboratory may choose the free Lab Advantage option, which is a total quality approach to accreditation, proficiency testing, and technical education provided through a collaborative partnership with the American Proficiency Institute (API) and the American Society for Clinical Pathology (ASCP). Participants will receive a 5% discount on their Joint Commission laboratory annual fee and full laboratory survey fee plus a 10% discount from ASCP on educational programs. To participate, labs must enter their API number into their Joint Commission lab E-App. For more information, refer to the website http://www.LabAdvantage.org or e-mail the Lab Advantage Coordinator at info@labadvantage.org.

Survey Agenda

The Joint Commission reviews the data in a laboratory’s E-App and posts a sample agenda on the organization’s secure Joint Commission Connect site. Also available on the secure site is the Survey Activity Guide, which includes a list of initial materials the surveyor will request to review at the onset of the survey.
The organization’s Joint Commission account executive will contact the laboratory and provide the anticipated number of days and number of surveyors that will be assigned for the on-site survey. On the first day of an on-site survey, the surveyor(s) will work with the laboratory to ensure the schedule considers the organization’s operations and needs. During the survey, the surveyor(s) will work to minimize any disruption to patient care when conducting survey activities.

The on-site survey process focuses on continuous operational improvement in support of safe, high-quality care, treatment, and services. The survey agenda will include the elements described in the following paragraphs.

**Surveyor Arrival and Preliminary Planning Session.** Upon arrival, surveyors will check in with reception, present their identification, and indicate their purpose for visiting. Staff should be prepared with a plan and instructions for how to proceed. The surveyor(s) will want to get settled in and begin reviewing the documentation identified in the Document List as soon as possible.

**Opening Conference and Orientation to the Organization.** During the opening conference, the surveyor(s) describes the structure and content of the survey to organization staff. Surveyors will take time to introduce your organization to the revised clarification procedures and new Survey Analysis for Evaluating Risk™ (SAFER™) reporting process. During the time designated for the orientation, staff provide the surveyor(s) with information about the organization. At this time, the laboratory will briefly explain its structures, mission, vision, and relationship with the community. This provides the surveyor(s) with baseline information about the organization that can help focus subsequent survey activities.

**Regulatory Review.** During this session, the surveyor(s) will review the CLIA certificates for director and specialty/subspecialty information, applicable licenses, test volumes, and Individualized Quality Control Plan (IQCP) documentation.

**Proficiency Testing/Validation/Performance Improvement Data Review.** During the proficiency testing validation review session, the surveyor will review proficiency testing enrollment, participation, and performance for regulated analytes; proficiency testing performance for tests not requiring proficiency testing by law (nonregulated analytes), if applicable; and performance improvement data.

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Please see the *Survey Activity Guide* on the *Joint Commission Connect* site or at https://www.jointcommission.org/2017_survey_activity_guide/ for more detailed information on the survey process.
**Surveyor Planning Session.** During this session, the surveyor(s) will review data and information about the laboratory to plan the survey agenda. This will include any information from previously conducted Joint Commission activities and other laboratory documents that have been gathered for review. The surveyor(s) will select the first patients for tracing based on what he or she learns from the review of data and information during this session.

**Individual Tracer Activity.** During the individual tracer activity, the surveyor(s) will do the following:

- Follow the course of care, treatment, or services provided to the patient by the laboratory
- Assess the interrelationships among disciplines and services/programs and the important functions in the care, treatment, or services provided
- Evaluate the performance of processes relevant to the care, treatment, or service needs of the patient, with particular focus on the integration and coordination of distinct but related processes
- Identify vulnerabilities in the care processes

See the “Tracer Methodology” section for more information.

**Issue Resolution.** This session provides an opportunity for the surveyor(s) to follow up on potential findings that could not be resolved in other survey activities.

**Surveyor Team Meeting/Planning Session.** This time is reserved for the surveyor(s) to review and analyze the information gathered throughout the day and plan for upcoming survey activities.

**Daily Briefings.** During the daily briefing session, surveyors will communicate to organization staff their observations on the previous day’s survey findings and any significant patterns or trends that are becoming evident in the survey, if requested to do so. During the daily briefing, the surveyor(s) will do the following:

- Facilitate leaders’ understanding of the survey process and the findings
- Report on findings from the previous day’s survey activities, including the placement of findings up to that point on the SAFER Matrix (note that placement of findings on the matrix is subject to change as the survey progresses and there may be additional findings)
- Emphasize patterns or trends of significant concern that could lead to noncompliance determinations
- Highlight any positive findings or exemplary performance
Allow the organization to supply additional information that would demonstrate compliance with a standard that a surveyor has indicated may be an RFI

Review the agenda for the survey day ahead and make any necessary adjustments based on laboratory needs or the need for more intensive assessment of an issue

If the organization has additional information that would demonstrate compliance with a standard that a surveyor has indicated may be an RFI, the organization should supply that information to the surveyor(s) as soon as possible.

**Surveyor Report Preparation.** The surveyor(s) will use this time to compile, analyze, and organize the data he or she has collected throughout the survey into a preliminary Summary of Survey Findings Report reflecting the organization’s compliance with standards (see the “Summary of Survey Findings Report” section).

**Exit Briefing and Organization Exit Conference.** The surveyor will offer to meet with the most senior leader, usually the CEO or administrator, or the leadership team to conduct a private Exit Briefing. During the Exit Briefing, the surveyor will present the survey findings and review the preliminary Summary of Survey Findings Report (including the SAFER Matrix results), discuss any concerns senior leaders have with the report, and determine the need for any special arrangements for the Organization Exit Conference.

During the Organization Exit Conference the surveyor(s) will review the survey findings (if desired by senior leaders), review the issues of standards compliance that have been identified during the survey, and review required follow-up actions, as applicable.

**Tracer Methodology**

The tracer methodology is the cornerstone of The Joint Commission on-site survey. The tracer methodology incorporates the use of information the organization supplies in the E-App to follow the experience of care, treatment, or services for a number of individuals through the organization’s entire health care delivery process. Tracers allow the surveyor(s) to identify performance issues in one or more steps of the process or in the interfaces between processes. Laboratory surveys involve individual tracer activities, as described in the following section.
Individual Tracer Activity

The individual tracer activity is conducted during an on-site survey and is designed to “trace” the care experiences that a patient had while at the laboratory. The tracer methodology is a way to analyze a laboratory’s system of providing care, treatment, or services using actual patients as the framework for assessing standards compliance. The surveyor(s) will use the following general criteria to select initial individual tracers:

- Patients whose tracers would allow for the evaluation of identified program-specific risk areas/categories (EPs with the R icon).
- Patients who cross programs (for example, home care patients discharged from a hospital or individuals served by behavioral health care organizations who present at an ambulatory care facility in complex organizations)
- Patients receiving complex services, such as surgery or treatment in an intensive care unit

Patients selected for initial individual tracer activity will likely be those whose diagnosis, age, or type of services received may enable the best in-depth evaluation of the laboratory’s processes and practices. In conducting a patient’s tracer, the surveyor(s) will follow specific patients through the laboratory’s processes. A surveyor will not only examine the individual components of a system but will also evaluate how the components of a system interact with each other. In other words, a surveyor will look at the care, treatment, or services provided by each department/unit/program and service, as well as how departments/units/programs and services work together. The surveyor(s) usually starts where the patient is currently located. He or she can then move to where the patient first entered the organization’s systems; an area of care provided to the patient that may be a priority for that organization; or to any areas in which the patient received care, treatment, or services. The location and order will vary. Along the way, the surveyor(s) will speak with the health care staff member(s) who actually provided the care to that individual tracer patient—or, if that staff member(s) is not available, will speak with another staff member(s) who provides the same type of care, treatment, or services.

Based on the findings of the surveyor(s), he or she may select similar patients to trace. The tracer methodology permits surveyors to further investigate if there is a reason to believe that an issue needs further exploration.

Please see the Survey Activity Guide on the Joint Commission Connect for more detailed information on other program-specific criteria for tracer selection.
Risk Areas
A surveyor conducting any type of tracer at a laboratory might notice something that requires a more in-depth look. At that point, the surveyor will look at all processes at a system level by asking more detailed questions or spending more time looking at a particular risk area. The focused evaluation includes processes or procedures that, if not planned or implemented correctly, have significant potential for affecting/impacting patient safety. Examples of topics that surveyors might need to explore in more detail at laboratories are nonwaived and Provider-Performed Microscopy Procedure (PPMP) competencies.

Surveyors will assess and display the risk associated with findings by utilizing the SAFER Matrix. Survey findings will be plotted on the SAFER Matrix according to the likelihood the RFI could cause harm to patients, staff, and/or visitors and the scope at which the RFI was observed.

The Role of Staff in Tracer Methodology
To help the surveyor(s) in the tracer methodology process, staff will be asked to provide the surveyor(s) with a list of active patients, including the patients’ names, current locations in the laboratory, and diagnoses/conditions, as appropriate. The surveyor(s) may request assistance from laboratory staff for selection of appropriate tracer patients. As the surveyor(s) moves around a laboratory, he or she will ask to speak with the staff members who have been involved in the tracer patient’s care, treatment, or services if available. If those staff members are not available, the surveyor(s) will ask to speak to another staff member who would perform the same function(s) as the member who has provided services for the tracer patient. Although it is preferable to speak with the testing personnel, it is not mandatory because the questions that will be asked are questions that any testing personnel should be able to answer in providing care, treatment, or service to the patient being traced.

Immediate Threat to Health or Safety
The Joint Commission defines Immediate Threat to Health or Safety as “a threat that represents immediate risk and has or may potentially have serious adverse effects on the health or safety of the patient, resident, or individual served.” Such a situation may occur anywhere in an organization. (See Accreditation Participation Requirement [APR].09.04.01.)
If a surveyor identifies any condition that he or she believes poses a serious threat to public or patient health or safety, he or she will notify the organization’s CEO and Joint Commission headquarters staff immediately. The president of The Joint Commission, or his or her designee, can then issue an expedited Preliminary Denial of Accreditation decision based on the threat. An organization notified of a Preliminary Denial of Accreditation decision due to an Immediate Threat to Health or Safety situation does not have a right to “clarify” the survey findings relative to the situation. Since a Preliminary Denial of Accreditation is an official accreditation decision category, the decision is posted on Quality Check.

The organization’s CEO and appropriate governmental authorities are informed of this decision and the findings that led to this action. After notification of the Preliminary Denial of Accreditation decision, an organization has up to 72 hours to do the following:

- Eliminate the Immediate Threat to Health or Safety situation entirely
- If the situation is such that it will take the organization more time to fully eliminate it (such as situations involving building construction), then the organization must implement emergency interventions†† to abate the risk to patients (for example, cease performing a certain procedure, implement additional safety measures) within 72 hours. If the situation is not fully eliminated within 72 hours, the organization will have a maximum of 23 calendar days to do so.

At its next meeting, executive leadership can either confirm or reverse the Preliminary Denial of Accreditation decision by the president or his/her designee. Executive leadership may take into consideration an organization’s corrective actions or responses to a serious threat situation. The organization can provide information to demonstrate that a serious threat to health or safety has been corrected prior to executive leadership’s consideration of the Preliminary Denial of Accreditation decision.

In these situations, the corrective action is considered when a single issue leads to the adverse finding and the organization demonstrates that it did the following:

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After the Preliminary Denial of Accreditation decision has been confirmed by the Joint Commission’s executive leadership, the organization has five days to notify The Joint Commission if it wishes to appeal the decision. If this is the case, The Joint Commission’s Review and Appeal Procedures apply.

†† Emergency intervention refers to any safety measure implemented to preserve life, whether related to Life Safety Code® deficiencies or another Immediate Threat to Health or Safety situation. When referring to specific Life Safety Code issues, these interventions would be called interim life safety measures, which are defined as “a series of 11 administrative actions intended to temporarily compensate for significant hazards posed by existing National Fire Protection Association 101-2012 Life Safety Code deficiencies or construction activities.”
- Took immediate action to completely remedy the situation
- Adopted systems changes to prevent a future recurrence of the problem

If the organization demonstrates that it has taken corrective action, The Joint Commission will conduct an abatement survey to validate the implementation of the corrective action and that the immediate threat situation is no longer present.

The results of the abatement survey will help The Joint Commission determine whether to remove the Preliminary Denial of Accreditation decision (assuming there are no other reasons for the Preliminary Denial of Accreditation). Therefore, the sooner an organization eliminates the Immediate Threat to Health or Safety situation, the shorter the period of time the organization may be in Preliminary Denial of Accreditation.

Upon resolution of an Immediate Threat to Health or Safety situation, the organization’s accreditation status may change from Preliminary Denial of Accreditation (PDA) to a time-limited PDA and Accreditation with Follow-up Survey and remain as such until an accreditation follow-up survey is conducted to assess the organization’s sustained implementation of appropriate corrective actions.

See Figure 2 for a visual representation of the process flow for Immediate Threat to Health or Safety situations at organizations seeking reaccreditation.

**Immediate Threat to Health or Safety During Initial Survey**

There are only two possible outcomes—Accredited or Denial of Accreditation—for an organization undergoing its first, or initial, Joint Commission survey; therefore, initial organizations that have an Immediate Threat to Health or Safety situation will receive a Denial of Accreditation decision with no opportunity for an appeal. Once the Immediate Threat to Health or Safety situation is identified, the organization will not be able to withdraw from the accreditation process. In addition, The Joint Commission will notify the licensing authority having jurisdiction that the organization was denied accreditation due to the Immediate Threat to Health or Safety. If the organization decides to reapply after the appropriate time interval (a minimum of four months), it will undergo a survey to demonstrate that it has abated the Immediate Threat to Health or Safety. This survey may be conducted before—or in conjunction with—the full survey.
Figure 2. Process flow for Immediate Threat to Health or Safety (ITHS) situations at organizations seeking reaccreditation.
The Summary of Survey Findings Report

Following evaluation of an organization’s performance of functions and processes, the surveyor (or survey team) reviews the results of integrated individual findings. Then, with the use of laptop-based support software, the surveyor (or survey team) posts the organization’s preliminary Summary of Survey Findings Report to the organization’s extranet site. Included in this preliminary report is the Survey Analysis for Evaluating Risk™ (SAFER™) Matrix, which gives a visual representation of the risk level of each RFI. If requested, the surveyor (or survey team leader) and the organization’s CEO meet prior to the closing conference to determine how the report will be shared (in terms of detailed, summary, or general comments) at the closing conference. The surveyor (or survey team) uses the report contents in making closing conference presentations.

Shortly after a survey, an organization’s report of survey findings is posted on the organization’s secure Joint Commission Connect site. The report includes RFIs, as appropriate. Each RFI will be plotted on the SAFER Matrix according to the risk level of the finding—that is, the likelihood of the finding to cause harm to patients, staff, and/or visitors and the scope at which the RFI was observed. If a laboratory does not receive any RFIs, its accreditation decision is rendered at the same time that the laboratory’s preliminary Summary of Survey Findings Report is available, and it is effective the day after the completion of the survey. If a laboratory does receive RFIs, then its accreditation decision is rendered following the submission of an acceptable ESC report. (See the “Accreditation Effective Date” section and the “Evidence of Standards Compliance [ESC] Process” section for more information.)

After the Survey

This section includes information relevant to an organization that has recently participated in an accreditation survey. Material includes information on scoring, the types of accreditation decisions, the ESC and clarification processes, how to request the review of an accreditation decision, how to appeal an accreditation decision, and how to use and display an accreditation award.

The Scoring Process

The performance expectations for determining if a standard is in compliance are included in its Elements of Performance (EPs). If an EP is determined to be out of compliance, then it will be cited as a Requirement for Improvement (RFI). Each RFI is placed in the SAFER Matrix according to how likely it is that the RFI will harm a patient(s), staff, and/
or visitor (low, moderate, high) and the scope, or prevalence, at which the RFI was cited (limited, pattern, widespread). As the risk level of a finding or an observation increases, the placement of the standard and EP moves from the bottom left corner (lowest risk level) to the upper right corner (highest risk level). Figure 3 is a representation of the SAFER Matrix.

The SAFER Matrix is the visual representation of risk associated with survey findings. If a standard is not applicable (NA) to the organization, it will be marked “NA” and not placed within the SAFER Matrix.

**How Accreditation Decisions Are Made**
Accreditation decisions are made based on the premise that the immediacy of risk to quality of care and patient safety—as shown by noncompliance with Joint Commission standards and EPs—varies. All noncompliant EPs will be cited as RFIs. In addition, all RFIs must be addressed via the ESC submission process. The time frame for completing
the ESC submission is within 60 calendar days. However, organizations recommended for Preliminary Denial of Accreditation decision PDA02 (as a result of patients being placed at risk for a serious adverse outcome due to significant and pervasive patterns, trends, and/or repeat findings) are required to submit a Plan of Correction (POC) within 10 business days instead of an ESC. A validation survey will be required within 60 days to confirm that the organization has implemented the POC and is in full compliance.

The organization’s accreditation decision will be held in abeyance pending submission of ESC within the established time frame. For situations that constitute more immediate risks to quality of care and patient safety, a more severe accreditation status will be applied. In these scenarios, the two accreditation classifications defined below will be utilized:

- Immediate Threat to Health or Safety
- Decision Rules

**Immediate Threat to Health or Safety.** Immediate Threat to Health or Safety situations that are identified on site have or may potentially have serious adverse effects on the health or safety of patients. Upon resolution of an Immediate Threat to Health or Safety situation, the organization’s accreditation status may change from Preliminary Denial of Accreditation to Accreditation with Follow-up Survey and remain as such until a follow-up survey is conducted to assess the organization’s sustained implementation of appropriate corrective actions.

Immediate Threat to Health or Safety situations are cited at Accreditation Participation Requirement APR.09.04.01, EP 1.

**Decision Rules.** Decision rules determine an accreditation decision that appropriately represents an organization’s overall performance as measured by noncompliance with the applicable standards. Decision rules are applied when a heightened risk to patient care and safety is determined as a result of on-site survey findings. There are times when situations will automatically trigger a recommendation for Preliminary Denial of Accreditation or Accreditation with Follow-up Survey based on such issues as loss of facility licensure, provision of care by unlicensed individuals who require such a license, and failure to send proficiency testing samples to another laboratory for analysis. In follow-up to these situations, organizations must demonstrate resolution of the situation through the ESC process. An on-site survey is conducted to validate implementation of corrective action.
For more information regarding decision rules, see the “Decision Rules for Organizations Seeking Reaccreditation” and “Decision Rules for Organizations Seeking Initial Accreditation” sections later in this chapter.

The Accreditation Decision Process
The goal of the accreditation decision and reporting approach is to focus attention on the issues that pose the greatest risk to quality of care, treatment, and services and to patient safety. Key elements of the accreditation decision process include the following:

- Levels of noncompliance with Joint Commission standards are identified on the SAFER Matrix.
- The surveyor(s) leaves a preliminary Summary of Survey Findings Report on site. (For special surveys, no report is left on site.)
- The Accreditation Survey Findings Report will be posted on the laboratory’s secure extranet site within 10 business days of the survey’s completion.
- If RFIs are cited, the organization has a 60-day window to submit an ESC report to address correction of the RFIs.
- Organizations that receive a PDA02 decision must submit a POC (instead of an ESC) within 10 business days; a validation survey is conducted within 60 days to confirm that the POC has been implemented and the organization is in full compliance.

The “Joint Commission Findings” section of the Accreditation Survey Findings Report includes RFIs and associated findings cited during the on-site survey. In addition, Joint Commission EPs that are initially identified as less-than-fully compliant but corrected before the conclusion of the survey are designated as Observed but Corrected On-site (OBC). Although the OBC indicator recognizes issues as having been “fixed” before the conclusion of the survey, these RFIs remain in the survey report; that is, an ESC still needs to be completed for these findings.

Decision Categories for Organizations Seeking Accreditation Renewal
The Joint Commission’s decision categories are designed to help distinguish organizations with serious patterns and trends in the provision of care, treatment, or services—which require follow-up more quickly—from those with less serious compliance issues. There are four possible decision categories for organizations undergoing a Joint
Commission survey for reaccreditation. Figure 4 illustrates the continuum of accreditation decisions possible following resurvey activity. The Joint Commission’s four accreditation decision categories for organizations seeking renewal of accreditation are as follows:

1. **Accredited.** The organization is in compliance with all applicable requirements at the time of the on-site survey or has successfully addressed all RFIs in an ESC within 60 days following the posting of the Accreditation Survey Findings Report and does not meet any other rules for other accreditation decisions.

2. **Accreditation with Follow-up Survey.** The organization is in compliance with all standards as determined by an acceptable ESC submission. A follow-up survey is required within six months to assess sustained compliance.

3. **Preliminary Denial of Accreditation.** There is justification to deny accreditation to the organization as evidenced by
   - An Immediate Threat to Health or Safety to patients or the public, and/or
   - Submission of falsified documents or misrepresented information, and/or
   - Lack of a required license or similar issue at the time of survey, and/or
   - Failure to resolve the requirements of Accreditation with Follow-up Survey, and/or
   - Significant noncompliance with Joint Commission standards.

   In some circumstances, a decision of Preliminary Denial of Accreditation is subject to review and appeal prior to the determination to deny accreditation. (See the “Appeal Procedures” section.)

4. **Denial of Accreditation.** The organization has been denied accreditation. All available review and appeal opportunities have been exhausted.

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There is a fifth decision category for organizations seeking initial accreditation: Limited, Temporary Accreditation. As explained in the “Early Survey Policy” section earlier in this chapter, an organization receives this decision if it demonstrates compliance with the limited set of standards surveyed in the first survey under the Early Survey Policy.
### Decision Outcomes for Organizations Seeking Initial Accreditation

For organizations undergoing their first, or initial, Joint Commission survey, the decision process may result in only two possible outcomes—Accredited or Denial of Accreditation. Initial organizations receive an Accredited decision when they are in compliance with all applicable requirements at the time of the on-site survey or when they have successfully addressed all RFIs in an ESC within 60 days; if they do not successfully address all RFIs in an ESC within 60 days, they receive a Denial of Accreditation decision.

During the 60-day time frame, the decision is pending and the process is as follows: Organizations found out of compliance with Joint Commission requirements during their initial survey may voluntarily withdraw from the accreditation process with no decision rendered if they have not yet submitted their ESC in the allotted time. If they do not withdraw, initial organizations must submit corrective action through an ESC. Again, a successful ESC will then result in an Accredited decision. If an ESC is unacceptable because it does not demonstrate compliance, a decision of Denial of Accreditation—with no opportunity to appeal—will result.

<table>
<thead>
<tr>
<th>Decision Outcomes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accredited</td>
<td>Organizations in compliance with all applicable requirements</td>
</tr>
<tr>
<td>Accreditation with</td>
<td>Organizations have successfully addressed all RFIs in an ESC</td>
</tr>
<tr>
<td>Follow-up Survey</td>
<td>within 60 days.</td>
</tr>
<tr>
<td>Preliminary Denial</td>
<td>Organizations not in compliance but have started corrective</td>
</tr>
<tr>
<td>of Accreditation</td>
<td>action process.</td>
</tr>
<tr>
<td>Denial of Accreditation</td>
<td>Organizations not in compliance and have not started corrective action.</td>
</tr>
</tbody>
</table>
Accreditation Effective Date
For accredited organizations undergoing a resurvey, the effective date of the accreditation decision varies. (See the “Evidence of Standards Compliance (ESC) Process” section for more information.) For organizations that do not receive any RFIs, the accreditation decision will be effective the day after the last day of survey. Otherwise, an accreditation decision is rendered following the submission of an acceptable ESC report, which is retroactive to the day after the last day of the full survey.

The accreditation effective date for an organization that undergoes an initial survey is the date on which the last acceptable ESC was submitted, if the organization has an RFI. If there are no RFIs, the effective date is the day after the last day of the survey.

When an organization’s accreditation decision becomes official, it is publicly disclosable and is posted on Quality Check. In addition, the Requirements for Improvement will be posted for those organizations that receive a Preliminary Denial of Accreditation.

Withdrawing or Closing After Undergoing a Resurvey
An accredited organization’s request to withdraw from the accreditation process after undergoing a resurvey (or that closes after undergoing survey), but before a final decision has been made, does not terminate the decision-making process. The Joint Commission then issues a final accreditation decision.

Withdrawing from Initial Survey
An organization has the opportunity to withdraw from an initial survey up until the time it submits an ESC—which could be on site or shortly thereafter. If the organization requests to withdraw from the survey after it submits an ESC, the request will be denied and the organization will receive a decision of Denial of Accreditation with no opportunity to appeal.

Evidence of Standards Compliance (ESC) Process
An ESC is a report submitted by a surveyed laboratory that details the action(s) that it took to bring itself into compliance with a standard. The ESC report is available for completion on the laboratory’s secure Joint Commission Connect site at the same time that the laboratory’s Summary of Survey Findings report is posted.
After the survey, the surveyor(s) transmits his or her survey findings to the Joint Commission’s Central Office. The organization’s official Accreditation Survey Findings Report will be posted on its secure Joint Commission Connect site within 10 business days of completing a survey.

Every standard found not in compliance at the time of survey will generate an RFI. When a laboratory receives an RFI, it can choose to go directly to corrective action or to try and clarify the accuracy of the RFI. The organization must submit either a successful clarification or a corrective ESC for every RFI cited in a laboratory’s Accreditation Survey Findings Report (see the “Standards Clarification” section). Challenging specific surveyor observations will not result in the automatic removal of an RFI. The time frame for submitting a corrective ESC is 60 days. A corrective ESC must address compliance at the EP level for all applicable corrections.

For those findings of a higher risk level, additional fields will be required within the ESC for the organization to provide a more detailed description of the leadership involvement and preventive analysis that will assist in sustaining the compliance plan. In addition, these higher risk findings will be provided to surveyors for possible review or on-site validation during any on-site surveys up until the next full biennial survey occurs. The SAFER Matrix information in Figure 5 provides a representation of possible ESC follow-up activities for RFIs of varying risk levels.

<table>
<thead>
<tr>
<th>SAFER Matrix™ Placement</th>
<th>Required Follow-Up Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH/LIMITED, HIGH/PATTERN, HIGH/WIDESPREAD</td>
<td>• 60-day Evidence of Standards Compliance (ESC) that details the action(s) taken to come into compliance with the standards</td>
</tr>
<tr>
<td></td>
<td>• ESC will also include two additional areas surrounding the following:</td>
</tr>
<tr>
<td></td>
<td>(1) Leadership Involvement</td>
</tr>
<tr>
<td></td>
<td>(2) Preventive Analysis</td>
</tr>
<tr>
<td>MODERATE/PATTERN, MODERATE/WIDESPREAD</td>
<td>• Finding will be highlighted for potential review by surveyors on subsequent on-site surveys up to and including the next full survey.</td>
</tr>
<tr>
<td>MODERATE/LIMITED, LOW/PATTERN, LOW/WIDESPREAD</td>
<td>• 60-day Evidence of Standards Compliance (ESC) that details the action(s) taken to come into compliance with the standards</td>
</tr>
<tr>
<td>LOW/LIMITED</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 5.** SAFER Matrix placement and required follow-up activities.
Standards Clarification

After a survey event, organizations have the opportunity to submit clarifying ESC if they believe that their organization was in compliance with a particular standard at the time of survey. (This process does not include EPs initially identified as noncompliant but corrected before the survey’s conclusion. Also not included in this process is the placement of a finding within the SAFER Matrix; that is, an organization can clarify the finding as a whole but cannot change where the finding is placed within the matrix.)

The “clarification” is part of the ESC process and must be submitted within 10 business days following the posting of the organization’s report on the Joint Commission Connect site. The submission of a clarification does not negate the requirement for submission of a corrective ESC within 60 days if the clarification does not remove the RFI, nor does it provide an organization with additional time to submit its ESC. Therefore, if an organization submits clarification and still has to submit an ESC, the organization will have up to 60 days in total to submit both the clarification and the corrective ESC.

When submitting clarifying ESCs after a survey event, it is important to follow the directions in the submission tool. Address each prompt, detailing why the organization was in compliance at the time of survey. Remember to address the EP as well as the actual surveyor observation. (A finding of “lack of required documentation at the time of survey” is not eligible for clarification because documentation must be available for review at the time of survey—not after the survey.)

Corrective ESC

An acceptable corrective ESC report must detail the following:

- Compliance at the EP level
- Action(s), along with the final date of such action(s), that the organization took to bring itself into compliance with a requirement
- Title of the staff member ultimately responsible for implementing the corrective actions and sustaining compliance
- The plan for sustaining compliance
- Leadership involvement in the corrective action and sustained compliance plan (for those RFIs within the high-risk boxes on the SAFER Matrix, see Figure 5)
- Preventive analysis (for those RFIs within the high-risk boxes on the SAFER Matrix, see Figure 5)
An acceptable ESC report is due within 60 calendar days following the posting of the Accreditation Survey Findings Report (unless the laboratory is recommended for a PDA02 decision, in which case it must submit a POC within 10 business days and undergo a validation survey within 60 days). The required time frame will be specified in the survey report. Following a successful submission of the ESC report, the organization receives an accreditation decision. However, the organization’s accreditation decision is retroactive to the day after the last day of the survey, unless the organization is undergoing its first Joint Commission survey. The accreditation effective date for an organization that undergoes an initial survey is the date on which an acceptable ESC was submitted, if the organization has any RFIs. If there are no RFIs, the effective date is the day after the last day of the survey.

If the organization implements acceptable actions to address its RFIs, the organization’s accreditation decision is Accredited.

The organization’s ESC submission(s) will be evaluated by Central Office staff using the same scoring guidelines used by the surveyors at the time of survey and by health care organizations when they conduct their FSA. The Joint Commission will consider the ESC acceptable when the laboratory has demonstrated resolution of all RFIs. If the laboratory has not met a rule for Accreditation with Follow-up Survey or Preliminary Denial of Accreditation, and the ESC submission(s) is determined to be acceptable, its decision will be Accredited.

**On-Site ESC.** Usually the ESC will be an electronic submission to The Joint Commission; however, on occasion, a review of the ESC may also be conducted on site by a surveyor. If an on-site evaluation is required to assess compliance with the relevant standards following electronic submission, a copy of the laboratory’s electronic ESC is provided to the surveyor conducting the on-site ESC. The on-site ESC process provides the opportunity to evaluate the organization’s success in correcting the issues. It also allows the surveyor to provide coaching and guidance to the organization, supporting its efforts to achieve and maintain compliance with the standards.

A final decision letter will be posted to the laboratory’s secure, password-protected Joint Commission Connect site when its ESC has been reviewed and an accreditation decision has been rendered. A Quality Report will then be posted on Quality Check on The Joint Commission’s website. For more information, see “The Joint Commission Quality Report” (QR) chapter.
Accreditation Award Display and Use

The Joint Commission provides each accredited organization with one certificate of accreditation per accreditation program. There is no charge for the initial certificate(s). Additional certificates may be purchased. Such requests should be sent to the certificate coordinator in the Division of Accreditation and Certification Operations at The Joint Commission.

The certificate and all copies remain The Joint Commission’s property. They must be returned if either of the following situations occurs:

- The organization is issued a new certificate, reflecting a name change
- The organization’s accreditation decision is changed, withdrawn, or denied for any reason

Accreditation award certificates include language about educating patients and their families on how to contact The Joint Commission. An organization accredited by The Joint Commission must be accurate in describing to the public the nature and meaning of its accreditation and its award. When an organization receives an accreditation award, The Joint Commission sends the organization guidelines for characterizing the accreditation award.

An organization may not engage in any false or misleading advertising of an accreditation award. Any such advertising may be grounds for The Joint Commission to deny accreditation. For example, an organization may not represent its accreditation as being awarded by any of The Joint Commission’s corporate members. These include the American College of Physicians, the American College of Surgeons, the American Dental Association, the American Hospital Association, and the American Medical Association. The Joint Commission has permission to reprint the seals of its corporate members on certificates of accreditation. However, these seals must not be reproduced or displayed separately from the certificate.

Any organization that materially misleads the public about any matter relating to its accreditation must undertake corrective advertising to a degree acceptable to The Joint Commission in the same medium in which the misrepresentation occurred. If an organization fails to undertake the required corrective advertising following the communication of false or misleading advertising about its accreditation decision, the organization may be subject to loss of accreditation.

The Joint Commission’s logo is a registered trademark. An accredited organization may use the logo if it follows these guidelines:
The logo must remain in the same proportional relationship as provided and should not be displayed any larger than an organization’s own logo.

The logo’s format cannot be changed, the name may not be separated from the symbol, and the logo must be printed in the original color.

Graphic devices such as seals, other words, or slogans cannot be added to the logo, except for the words “Accredited by.”

These guidelines apply to logo use on all print materials, Internet webpages, and promotional items, such as coffee mugs, T-shirts, and notepads.

Contact The Joint Commission Department of Communications at 630-792-5631 for questions about using The Joint Commission logo or access the Accreditation Publicity Kit online at http://www.jointcommission.org.

Between Accreditation Surveys
This section provides information that is relevant to organizations between Joint Commission surveys. Material includes the duration of an accreditation award, the process for continuing accreditation, the FSA process, how to notify The Joint Commission in the event of organization changes, and information on other types of surveys.

Duration of Accreditation Award
An accreditation award is continuous until the organization has its next full survey, which will be between 18 and 24 months after its previous full survey, unless accreditation is revoked for cause or as otherwise outlined in this chapter. An organization may request a full accreditation survey more frequently than when it is due to have a survey. The Joint Commission, at its discretion and in accordance with its mission, determines whether to honor the request. An organization should send such a request to its Joint Commission account executive.

An organization’s accreditation cycle is continuous, as long as the organization:
- Has a full, unannounced survey within approximately 24 months of its last survey; and
- Continues to meet all accreditation-related requirements as required, including, but not limited to, submission of an FSA (see “Focused Standards Assessment [FSA],” following) and an annual subscription payment.
Continuous Compliance

The Joint Commission expects an accredited organization to be in continuous compliance with all applicable standards and EPs. It may ask an organization to supply, in writing, information about compliance with applicable standards. The Joint Commission may conduct a survey if an organization fails to respond to a request for more information. It may also survey an organization at any time with or without notice in response to complaints, media coverage, or other information that raises questions about the adequacy of patient health and safety protections (see the “For-Cause Surveys” section for more information).

The Joint Commission may view an organization’s failure to permit a survey as the organization no longer wanting to participate in good faith in the accreditation process. In such a case, The Joint Commission begins proceedings to deny accreditation to the organization (see APR.02.01.01 in the APR chapter).

Intracycle Monitoring

To assist accredited organizations with their continuous compliance efforts, The Joint Commission makes the Intracycle Monitoring (ICM) Profile available on The Joint Commission Connect extranet site. The ICM Profile identifies high-risk areas and related standards for laboratories. These standards are displayed within the FSA tool with a special risk icon. The FSA tool enables organizations to conduct their own self-assessment of standards compliance throughout the biennial accreditation cycle.

The Joint Commission identifies critical systems/processes that could lead to adverse effects if they become weak or fail. Risk is assessed by a system’s proximity to the patient, probability of harm, severity of harm, and number of patients at risk. Risk categories in the FSA are related to the following three categories:

1. National Patient Safety Goals
2. Accreditation program–specific risk areas
3. RFIs identified during current accreditation cycle survey events

Focused Standards Assessment (FSA)

The FSA process is designed to help laboratories incorporate Joint Commission standards as part of routine operations and ongoing quality improvement efforts, supporting a continuous accreditation process. A laboratory has access to its FSA tool on a continuous basis throughout its accreditation cycle. The FSA tool becomes available to a laboratory
seeking accreditation for the first time after submitting its E-App and deposit. The FSA tool permits the laboratory to evaluate compliance with all applicable Joint Commission standards and EPs. For every noncompliant standard, the laboratory must identify a Plan of Action (POA) at the EP level, identifying how it plans to come into compliance with the requirement(s). By participating in the FSA, a laboratory will be better able to incorporate Joint Commission standards into routine operations, which in turn will help to ensure the provision of safe, high-quality care on an ongoing basis.

The FSA must be completed electronically through the Intracyle Monitoring (ICM) application located on the laboratory’s secure Joint Commission Connect site. The Joint Commission requires submission at the 12th month for lab applications (and at the 12th and 24th month for general applications). An FSA submission is not required the year the laboratory is scheduled for a full survey. Because full surveys can occur at any time between the 12th and 24th month of the biennial accreditation cycle, should a full survey occur before a laboratory’s anticipated FSA due date, the FSA due date will be reset accordingly. (Note that leadership of an organization with a PDA02 decision—a decision based on significant and pervasive patterns of noncompliant standards—is required to participate in the ICM process.) These submission intervals are valuable consultative and educational touch points to help organizations remain in continuous compliance with the standards and keep current with accreditation information. The tool and resources available are designed to provide educational support.

Organizations can select from one of the four ICM submission options. To accomplish a full submission, the minimum subset of standards coded with the icon must be scored as well as standards that have been scored as not compliant by the organization.

Organizations submitting Option 1 conduct and score their standards self-assessment but elect not to submit the data to The Joint Commission; however, they may still engage in a conference call with the Standards Interpretation Group to discuss topics of concern that are specific to their facility. Next are the on-site Option 2 and 3 surveys. These surveys are conducted by a Joint Commission surveyor for an additional fee. The Option 2 survey results in a written report of findings that the organization follows up with POAs as appropriate. An Option 3 survey provides the organization with a verbal report of survey findings but does not result in any historical written documentation.

Enhancements made to the FSA tool because of the SAFER process include two additional fields: Likelihood to Harm and Scope. These fields will only be displayed if an EP is scored as not compliant. Please note that if an organization scores an EP as not compliant, designating the likelihood to harm and scope is optional.
Sidebar 2 outlines some of the activities in each of these FSA options.

**Sidebar 2. Focused Standards Assessment Options**

### Full FSA
- Organization uses the FSA tool to assess and score compliance with EPs for each applicable standard.
- Organization creates a Plan of Action (POA) \(\text{§§§} \) addressing each EP scored as not compliant.
- Organization may elect to participate in a conference call with the Standards Interpretation Group (SIG) to discuss POAs or other standards-related issues of its choosing. If a conference call is not requested, the data will be reviewed by SIG. If SIG determines a conference call is needed, the organization will be contacted.
- Organizations submitting the Full FSA with noncompliant standards need to enter their conference call “avoid dates” when they submit their FSA. “Avoid dates” are dates on which the organization prefers that the conference call not be scheduled.
- If standards have been scored compliant and a call has not been requested, once the FSA is submitted, the ICM requirement for that particular year is completed and no further action is required.

### FSA Option 1
- Organization uses the FSA tool to assess and score compliance with EPs for each applicable standard if it chooses to do so.
- Organization affirms that it has completed an assessment of its compliance with applicable EPs and developed POAs as necessary, but it does not submit data to The Joint Commission.
- Organization can submit standards-related issues in the ICM Profile for telephone discussion with SIG, if desired.

### FSA Option 2
- Organizations that choose an Option 2 on-site survey will be charged a fee.
- The organization requests either an announced or unannounced FSA survey.
- Surveyor conducts the FSA survey using tracer methodology and identified accreditation program–specific risk areas; all standards are subject to review.
- Surveyor leaves a written report of findings with the organization.

\(\text{§§§} \) A Plan of Action details the action(s) an organization will take to come into compliance with each standard identified as not compliant.
Sidebar 2. (continued)

- SAFER Matrix is included during on-site visit and embedded within report.
- Within 30 calendar days of the survey, organization submits POAs for each noncompliant standard through the historical FSA tool.
- Organization may elect to participate in a conference call with SIG to discuss the POAs. If a conference call is not requested, the data will be reviewed by SIG. If SIG determines a conference call is needed, the organization will be contacted.
- SIG reviews and approves POAs during conference call.

**FSA Option 3**

- Organizations that choose an Option 3 on-site survey will be charged a fee.
- The organization requests either an announced or unannounced FSA survey.
- Surveyor conducts the FSA survey using tracer methodology and identified accreditation program–specific risk areas; all standards are subject to review.
- SAFER Matrix is included during on-site visit.
- Surveyor delivers an oral report of findings at the closing conference of the on-site survey. No written report of findings will be left at the organization.

The FSA will affect a laboratory’s accreditation decision only if the laboratory fails to participate in the FSA process, whether the Full FSA or one of the three options, or an Immediate Threat to Health or Safety situation is identified through the FSA process and a special survey is conducted. If you need more information while completing the FSA, please contact your account executive at 630-792-3007.

**Plan of Action (POA)**

A POA is a detailed description of how an organization plans to bring into compliance any standard identified as “not compliant” in the FSA. The POA must include the planned action to be taken and target implementation dates.

**Sentinel Event Follow-Up**

Accredited laboratories are expected to identify and respond appropriately to all sentinel events. The laboratory is required to conduct a thorough and credible comprehensive systematic analysis and develop a corrective action plan in a manner and time frame...
acceptable to The Joint Commission as specified in the Sentinel Event Policy and submit them to The Joint Commission or otherwise provide evidence of an acceptable response to the sentinel event. (See the “Sentinel Events” [SE] chapter for more information.)

**Notifying The Joint Commission About Organization Changes**

Accreditation is neither automatically transferred nor continued if significant changes occur within a laboratory. Laboratories must notify The Joint Commission promptly, in writing, when an additional service is contemplated so any potential impact to accreditation can be determined. Once the change has actually occurred, the E-App must be updated to reflect the change as well.

**Changes Affecting E-App Information**

At any time during the accreditation process, a laboratory may undergo a change that modifies the information reported in its E-App (see APR.01.03.01 in the APR chapter). Laboratories must notify The Joint Commission promptly, in writing, when an additional service or location is contemplated so any potential impact to accreditation can be determined. A laboratory may also be required to notify its state CLIA office for certain changes.

Once the change has actually occurred, the laboratory must update its E-App within 30 calendar days. Information that must be reported includes any of the following:

- A change in ownership
- A change in location
- A change in laboratory director
- A change in CLIA certificate type
- A significant increase or decrease in the volume of services or individuals served
- The addition of a new type of specialty or sub-specialty, program, or site of care
- The deletion of an existing specialty or sub-specialty, program, or site of care
- The addition of any high-complexity testing to the test menu
- The acquisition of a new component, for example, a new CLIA certificate
- The deletion of an existing component, for example, the deletion of a CLIA certificate

An organization is considered to have “contemplated” a change when leadership within the organization has approved moving forward with the proposed change and identified a time frame for implementing that change.
The Joint Commission may conduct an additional survey at a later date if its surveyor or survey team arrives at the laboratory and discovers that a change was not reported. The Joint Commission may also survey any unreported services and sites addressed by its standards during the survey as appropriate. The Joint Commission makes the final accreditation decision for the laboratory only after surveying all or an appropriate sample of all services, programs, and sites provided by the organization for which The Joint Commission has standards. Information reported in the E-App is subject to The Joint Commission’s Information Accuracy and Truthfulness Policy.

Changes to the Site of Care, Treatment, or Services
When a laboratory offers its services or programs at a new location or in a significantly altered physical plant, the laboratory must evaluate for Life Safety Code deficiencies and document the corrective actions (to be completed within 60 days of notification to The Joint Commission) and Interim Life Safety Measures (ILSM) implemented to protect the building occupants while the deficiencies are being corrected. Failure to provide timely notification to The Joint Commission of these conditions may result in the laboratory’s loss of accreditation. If the corrective actions cannot be accomplished within 60 days of notification to The Joint Commission, the laboratory will need to contact its Account Executive.

Mergers, Consolidations, and Acquisitions
In the case of a merger, consolidation, or acquisition, The Joint Commission may decide that the organization responsible for services must have a survey. If, after an organization receives an accreditation decision, the organization’s structure changes whereby one or more of its services, programs, or related laboratories are no longer part of the organization that was originally surveyed, the service, program, or related organization is no longer included in the organization’s accreditation.

See the “Extension Surveys” section for more information on what The Joint Commission expects to accomplish on these surveys.
Accreditation Status of Organizations That Cease Services After a Disaster

Following a disaster that requires a Joint Commission–accredited laboratory to cease the provision of services for a period of time, The Joint Commission will work with the affected laboratory to address the impact that the cessation of services will have on the laboratory’s accreditation status and to ensure that the laboratory is prepared to provide safe, quality care upon resumption of services. If after six months the laboratory cannot resume services, The Joint Commission will discontinue the accreditation of the laboratory. The impact of the cessation of services for a period of time on the accreditation status of organizations that experience a disaster is described below.

Cease Services Up to 30 Days. For laboratories that resume services within the first 30 days after a disaster and/or the laboratory’s decision to cease operations, the laboratory’s original Joint Commission accreditation status will stay in effect. The timeframe for complying with any outstanding Joint Commission requirements (such as the FSA or ESC) will pause until the laboratory resumes operation. In most cases, The Joint Commission will not need to survey the affected laboratory to reassess its level of standards compliance. If The Joint Commission decides to conduct a survey, however, the laboratory’s accreditation decision will be driven by the interim survey findings.

Cease Services Up to 90 Days. For laboratories that resume services from 31 to 90 days after a disaster, The Joint Commission will conduct an extension survey to determine the laboratory’s accreditation status. The circumstances surrounding the laboratory’s closure will determine the survey’s length and scope.

Cease Services Up to Six Months. For laboratories that resume services from 91 days up to six months after a disaster, The Joint Commission will require an on-site survey to assess the laboratory environment. This survey will preferably take place one to two weeks after services are resumed. These laboratories must receive clearance to operate from the fire marshal, if appropriate, and other local/state authorities before resuming services. In addition, The Joint Commission will conduct a second on-site survey approximately four months after services have been resumed to evaluate sustained compliance with Joint Commission standards and requirements. The track record requirement for demonstrating standards compliance will be four months.

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***Can be natural or man-made; any situation that causes cessation of services.
More Than Six Months. For laboratories that do not resume services within six months after a disaster or decide to cease operations, The Joint Commission will discontinue its accreditation. If the laboratory resumes services, it must reapply to become accredited. In such cases, the accreditation process will involve at least two surveys. The first survey will be conducted at the laboratory’s request and will assess the laboratory’s ability to provide safe patient care. The laboratory may qualify for an accreditation award as a result of this survey. The second survey will be conducted approximately four months later to assess sustained compliance with Joint Commission requirements. The track record requirement for demonstrating standards compliance will be four months.

The Joint Commission will continue to post on Quality Check all affected laboratories as Accredited up to six months after a disaster, unless interim survey findings dictate otherwise.

While working with affected health care organizations in the aftermath of a catastrophic event, The Joint Commission will be sensitive to these organizations’ needs and will work with responsible state and federal agencies to help reestablish the organizations’ operations as well as their qualification for accreditation.

If, following a disaster, a laboratory provides services at an alternate site, The Joint Commission will determine whether an extension survey or a full survey is required based on the scope of services being provided at the alternate site and the expected period of time that the services will be provided at the site.

If your laboratory is affected by a natural disaster, please notify your laboratory’s account executive as soon as possible. Once notified, The Joint Commission can cancel any accreditation-related events and offer assistance, if needed. If you don’t know who serves as your laboratory’s assigned account executive, please call 630-792-3007.

The above policy outlines a framework that The Joint Commission will generally follow when an organization is required to cease services for a period of time following a disaster. Depending on the unique circumstances of each situation, The Joint Commission may choose to modify this approach accordingly. In addition, The Joint Commission may coordinate its response with local, state, and/or federal officials having jurisdiction over the organization, as appropriate.
Accreditation Status of Organizations That Cease Services or Do Not Have Patients for a Period of Time

Joint Commission–accredited laboratories may stop providing care, treatment, and services to patients or may not have any patients for a period of time for reasons other than natural or man-made disasters. When a laboratory ceases to provide patient care services, it is required to notify The Joint Commission. The Joint Commission will work with the affected laboratory to address the impact that the cessation of services or the lack of patients will have on the laboratory’s accreditation status and to ensure that the laboratory is prepared to provide safe, quality care upon resumption of services. If after six months the laboratory cannot resume services, The Joint Commission will terminate the accreditation of the laboratory.

Up to 60 Days. If a laboratory does not have any patients for up to 60 days, The Joint Commission will continue the laboratory’s current accreditation status.

Up to Six Months. If a laboratory does not have any patients from 60 days to less than six months, but then resumes patient services within six months, The Joint Commission will continue the organization’s current accreditation status only if the organization has an extension survey. This extension survey would generally take place as soon as possible in accordance with the laboratory’s request. The purpose of this survey is to evaluate the laboratory’s capability for resuming services and whether it is performing at current accreditation levels. If the laboratory refuses an extension survey, the accreditation will be terminated.

More Than Six Months. If a laboratory does not have any patients for six months or longer, The Joint Commission will terminate the laboratory’s accreditation. If the laboratory resumes services, it will have to reapply for accreditation and have a full survey in order to evaluate its current compliance with Joint Commission standards.

Reentering the Accreditation Process

For a previously accredited organization to be designated as “new,” it must not have participated in the accreditation process during the previous four months. If an organization is reentering the accreditation process before four months have passed, it must demonstrate a continuous 12-month track record of compliance with the standards.
Additional Surveys
This section describes additional surveys that may occur during the accreditation cycle, including extension surveys, for-cause surveys, and other follow-up surveys.

Extension Surveys
The Joint Commission conducts an extension survey when an accredited laboratory acquires a new service, program, or site for which The Joint Commission has standards or significantly alters how it delivers care, treatment, or services. Extension surveys are performed to ensure that the accreditation decision previously awarded to the laboratory is still appropriate under the changed conditions. The results of an extension survey may affect the laboratory’s accreditation status.

An extension survey is conducted at an accredited laboratory or at a site that is owned and operated by the laboratory if the accredited laboratory’s current accreditation is not due to expire for at least 9 months and when at least one of the following conditions is met:

- Changed ownership and has a significant number of changes in the management and clinical staff or operating policies and procedures
- Offered services at a new location or in a significantly altered physical plant
- Expanded capacity to provide services by 50% or more, as measured by patient volume, pieces of equipment, or other relevant measures. This criterion will generate an extension survey only if there are also other changes at the organization.
- Provided a more intensive level of service

When an organization acquires a CLIA laboratory registration certificate, adds high-complexity testing, or upgrades a CLIA certificate of waiver or Certificate for PPMP to a Certificate of Accreditation, an extension survey will be conducted within 4 to 6 months to allow the organization time to bring a new service or site up to the accredited laboratory’s standard of performance. The survey findings resulting from the extension survey are maintained separately from, and are not reflected in, the accreditation decision of the acquiring organization for 12 months following the acquisition. The newly acquired component will be considered accredited during that period. After the extension survey, any outstanding standards compliance problems in the acquired component(s) are reflected in the accreditation decision of the acquiring organization.

*Per federal guidelines, a laboratory must obtain accreditation within 11 months of the issuance of a CLIA Laboratory Registration Certification number.
For-Cause Surveys
The Joint Commission may perform a for-cause survey when it becomes aware of potentially serious standards compliance or patient care, treatment, service, or safety issues or when it has other valid reasons for surveying an accredited organization (see APR.02.01.01 in the APR chapter).

Note: While The Joint Commission may conduct a for-cause survey within a full survey (as these surveys may be referred to the full survey team for investigation), for-cause unannounced surveys should not be confused with the regular unannounced surveys described in the “Survey Notification” section.

Such a survey can either include all the organization’s services or only those areas where a serious concern may exist.

A for-cause survey, which is usually unannounced, can take place at any point in an organization’s accreditation cycle. No on-site summary report is generated after a for-cause survey.

Note: An organization is charged for a for-cause survey. An organization can determine the cost of such a survey by calling the Joint Commission’s Pricing Unit at 630-792-5115.

The Joint Commission may deny an organization accreditation if the organization does not allow The Joint Commission to conduct an unscheduled or unannounced survey (see APR.02.01.01 in the APR chapter).

Random Validation of Evidence of Standards Compliance
On an annual basis, a 2% random sample of all laboratories that have been required to submit an ESC will be selected for an unannounced on-site validation survey that will take place soon after the ESC submission. The purpose of this survey is to maintain the credibility of the ESC process by validating statements made in the ESC submission. The surveyor will evaluate areas that were the subject of each RFI to determine whether the corrective actions were implemented as stated.

Decision Rules for Organizations Seeking Initial Accreditation
The Joint Commission makes accreditation decisions by applying decision rules to the scored standards. Decision rules determine an accreditation decision that appropriately represents an organization’s overall performance as measured by evidence of compliance
with the applicable standards. Decision rules are approved by executive leadership. Executive leadership may exercise reasonable discretion in individual cases to determine whether to vary from applicable decision rules in furtherance of The Joint Commission’s mission to help health care organizations to continuously improve health care for the public.

The decision rules for laboratories follow.

**Note:** Accreditation decision rules are numbered sequentially across all Joint Commission accreditation programs. Some accreditation decision rules do not apply to laboratories and are therefore not included in this accreditation manual. Consequently, gaps may appear in the sequence of the decision rules included in this section.

**Accredited**

Accreditation will be recommended when one or more of the following conditions are met:

- **A01** The laboratory is in compliance with all standards at the time of the on-site survey or has successfully addressed all RFIs in its first ESC submission and does not meet any rules for other accreditation decisions.

- **A02** The laboratory, as a result of an on-site follow-up survey, is compliant with the original survey RFIs.

  **Note:** Should additional RFIs be identified, appropriate decision rules apply.

**Limited, Temporary Accreditation**

Limited, Temporary Accreditation will be recommended when the following condition is met:

- **LTA01** The laboratory has demonstrated compliance with the selected standards used in the first survey conducted under the Early Survey Policy.

**Evidence of Standards Compliance (ESC)**

An ESC will be required when one or more of the following conditions are met:

- **ESC01** A laboratory has one or more noncompliant standards at the time of a survey event.
ESC02  A laboratory that fails to successfully address all RFIs in an ESC may be required to submit a second ESC.

ESC03  An on-site evaluation may be scheduled to validate compliance with the relevant standards in a written ESC.

**One-Month Survey**
A one-month survey will be performed when the following condition is met:

FOC01  A full laboratory survey will be conducted when a laboratory providing laboratory services cannot demonstrate to The Joint Commission that its laboratory accreditation decision is in good standing with a Joint Commission–recognized accreditor or the accreditation is more than 24 months old.

**Retrospective Cytology Survey**
A retrospective cytology survey will be scheduled within 45 days when the following condition is met:

FOC02  A retrospective cytology survey will be conducted if, during a full laboratory survey, a laboratory providing cytology services is observed to have quality issues in this specialty. This will require a special survey that includes, but is not limited to, a review of slides for diagnostic discrepancies, evaluation of policies and procedures, and verification of staff workload.

**Proficiency Testing Monitoring Survey**
A proficiency testing monitoring survey will be scheduled when the following condition is met:

PTM01  The laboratory has either initial or subsequent unsuccessful proficiency test performance and a determination is made that an on-site evaluation is required to assess either the plan of action or the plan for reinstatement when applicable, following cessation of testing (voluntary or involuntary).
Denial of Accreditation

Denial of Accreditation will be recommended when one or more of the following conditions are met:

**DA01** The laboratory does not permit the performance of any survey by The Joint Commission. (APR.02.01.01, EP 1)

**DA03** The laboratory has failed to submit payment for survey fees or annual fees.

**DA04** The laboratory has repeatedly failed to submit an ESC.

**DA05** A laboratory undergoing its first Joint Commission survey has placed patients at risk for a serious adverse outcome(s) due to significant and pervasive patterns and trends in survey findings.

**DA06** An Immediate Threat to Health or Safety exists for patients, staff, or the public within the laboratory undergoing its first Joint Commission survey. (APR.09.04.01, EP 1)

**DA07** The Joint Commission is reasonably persuaded that the laboratory submitted falsified documents or misrepresented information in any way in seeking to achieve accreditation. If accreditation is denied following implementation of this rule, the laboratory shall be prohibited from participating in the accreditation process for a period of one year unless the president of The Joint Commission, for good cause, waives all or a portion of this waiting period. (APR.01.02.01, EP 1)

**DA08** The laboratory undergoing its first Joint Commission survey fails to successfully address all RFIs in an ESC after two opportunities.

**DA10** The laboratory’s patients have been placed at risk for a serious adverse outcome because either an individual who does not possess a license, registration, or certification is providing or has provided health care services in the laboratory that would, under applicable law or regulation, require such a license, registration, or certification; or an individual is practicing outside the scope of his or her license, registration, or certification. (HR.01.02.07, EPs 1 and 2)

**DA11** The laboratory does not possess a license, certificate, and/or permit, as or when required by applicable law and regulation, to provide the health care services for which the laboratory is seeking accreditation. (LD.04.01.01, EP 1)
Decision Rules for Organizations Seeking Reaccreditation

**Accredited**
Accreditation will be recommended when one or more of the following conditions are met:

**A01** The laboratory is in compliance with all standards at the time of the on-site survey or has successfully addressed all RFIs in its first ESC submission and does not meet any rules for other accreditation decisions.

**A02** The laboratory, as a result of an on-site follow-up survey, is compliant with the original survey RFIs.

*Note:* Should additional RFIs be identified, appropriate decision rules apply.

**Evidence of Standards Compliance (ESC)**
An ESC will be required when one or more of the following conditions are met:

**ESC01** A laboratory has one or more noncompliant standards at the time of a survey event.

**ESC02** A laboratory that fails to successfully address all RFIs in an ESC may be required to submit a second ESC.

**One-Month Survey**
A one-month survey will be performed when the following condition is met:

**FOC01** A full laboratory survey will be conducted when a laboratory providing laboratory services cannot demonstrate to The Joint Commission that its laboratory accreditation decision is in good standing with a Joint Commission–recognized accreditor or the accreditation is more than 24 months old.

**Retrospective Cytology Survey**
A retrospective cytology survey will be scheduled within 45 days when the following condition is met:
FOC02  A retrospective cytology survey will be conducted if, during a full laboratory survey, a laboratory providing cytology services is observed to have quality issues in this specialty. This will require a special survey that includes, but is not limited to, a review of slides for diagnostic discrepancies, evaluation of policies and procedures, and verification of staff workload.

Proficiency Testing Monitoring Survey
A proficiency testing monitoring survey will be scheduled when the following condition is met:

PTM01  The laboratory has either initial or subsequent unsuccessful proficiency test performance and a determination is made that an on-site evaluation is required to assess either the plan of action or the plan for reinstatement when applicable, following cessation of testing (voluntary or involuntary).

Accreditation with Follow-up Survey

Note: The Accreditation with Follow-up Survey could occur within 30 days or up to six months after the decision is rendered.

Accreditation with Follow-up Survey will be recommended when one or more of the following conditions are met:

AFS01  The laboratory demonstrates systemic patterns, trends, and repeat findings with standards.

AFS03  The laboratory fails to successfully address all RFIs in an ESC after two opportunities.

AFS05  The laboratory, which has failed to resolve one or more of its original RFIs, may be scheduled for a second Accreditation with Follow-up Survey.

AFS06  The laboratory fails to participate in Intracycle Monitoring requirements.

AFS07  The laboratory fails to submit a written plan of action for unsuccessful proficiency testing after two requests from The Joint Commission.
An individual who does not possess a license, registration, or certification is providing or has provided health care services in the laboratory that would, under applicable law or regulation, require such a license, registration, or certification; or an individual is practicing outside the scope of his or her license, registration, or certification. (HR.01.02.07, EPs 1 and 2)

Note: Except as provided under rule PDA03.

If the Immediate Threat to Health or Safety abatement survey through direct observation or other determining method has demonstrated that the laboratory has implemented sufficient corrective action of the Immediate Threat, executive leadership may change the decision to Accreditation with Follow-up Survey.

There is some evidence that the laboratory may have engaged in possible fraud or abuse.

If a laboratory that has met the PDA02 decision rule has implemented sufficient corrective action as evidenced through an on-site validation survey, executive leadership may change the decision to Accreditation with Follow-up Survey.

Preliminary Denial of Accreditation

Preliminary Denial of Accreditation will be recommended when one or more of the following conditions are met:

An Immediate Threat to Health or Safety exists for patients, staff, or the public within the laboratory. (APR.09.04.01, EP 1)

The laboratory’s patients have been placed at risk for a serious adverse outcome(s) due to significant and pervasive patterns, trends, and/or repeat findings.

The laboratory’s patients have been placed at risk for a serious adverse outcome because either an individual who does not possess a license, registration, or certification is providing or has provided health care services in the laboratory that would, under applicable law or regulation, require such a license, registration, or certification; or an individual is practicing outside the scope of his or her license, registration, or certification. (HR.01.02.07, EPs 1 and 2)
PDA04  The laboratory does not possess a license, certificate, and/or permit, as or when required by applicable law and regulation, to provide the health care services for which the laboratory is seeking accreditation. (LD.04.01.01, EP 1)

PDA05  The Joint Commission is reasonably persuaded that the laboratory submitted falsified documents or misrepresented information in any way in seeking to achieve or retain accreditation. If accreditation is denied following implementation of this rule, the laboratory shall be prohibited from participating in the accreditation process for a period of one year unless the president of The Joint Commission, for good cause, waives all or a portion of this waiting period. (APR.01.02.01, EP 1)

PDA06  The laboratory with a decision of Accreditation with Follow-up Survey has failed to resolve all RFIs after two opportunities.

PDA07  The laboratory has failed to comply with a cease testing order issued by The Joint Commission, one of its cooperative partners, or a regulatory agency.

PDA08  The organization’s laboratory personnel have referred proficiency testing samples to another laboratory for analysis or participated in inter-laboratory communication regarding proficiency testing results before the results have been reported to the program provider. (QSA.01.04.01, EPs 1 and 2)

PDA10  The laboratory’s patients have been placed at risk for a serious adverse outcome because there is some evidence that the organization may have engaged in possible fraud or abuse.

PDA11  If the Immediate Threat to Health or Safety abatement survey through direct observation or other determining method has not demonstrated that the laboratory has implemented sufficient corrective action of the Immediate Threat, executive leadership will continue the decision of Preliminary Denial of Accreditation.

**Denial of Accreditation**

Denial of Accreditation will be recommended when one or more of the following conditions are met:

DA01  The laboratory does not permit the performance of any survey by The Joint Commission. (APR.02.01.01, EP 1)
The Accreditation Process

DA02  The laboratory has failed to resolve an Accreditation with Follow-up Survey status prior to withdrawing from the accreditation process.

DA03  The laboratory has failed to submit payment for survey fees or annual fees.

DA04  The laboratory has failed to submit an ESC or a Plan of Correction.

DA05  A laboratory in the sustaining improvement program fails to participate in Joint Commission intervention.

DA06  A laboratory has received a PDA decision in two sequential surveys.

Process for Organizations That Meet Decision Rule PDA02 for Patients Placed at Risk for Serious Adverse Outcomes Due to Significant and Pervasive Patterns, Trends, and/or Repeat Findings

The following process applies for organizations that receive a PDA02 decision:

- If an organization meets decision rule PDA02, the organization will be notified within 10 business days of the completion of its survey when its final report is posted on its extranet site.

- An organization will have the option of clarifying any inaccurate survey findings within 10 business days of the posting of the final report. The organization may waive this clarification option.

- Once the clarification is completed or waived, a Plan of Correction (POC) will be required within 10 business days. The POC must address all RFIs cited in the organization’s survey report.

**Note:** Organizations that fail to submit any timely POC will receive an automatic Denial of Accreditation with no opportunity to appeal.

- Following submission of a POC, an unannounced PDA validation survey will occur within approximately two months (60 calendar days) from the posting date of the final survey report. The validation survey will review implementation of the corrective actions identified in the POC.

  - If the PDA validation survey is successful, the organization may receive a time-limited PDA and Accreditation with Follow-up Survey thereafter.
If the validation survey is unsuccessful, the PDA status continues and the organization may appeal the PDA decision to a Review Hearing Panel. If an organization fails to appeal the continued PDA, the PDA decision becomes a final Denial of Accreditation within 5 business days of being notified of the continued PDA.

Following a PDA validation survey that results in a time-limited PDA with an Accreditation with Follow-up Survey decision, The Joint Commission’s Chief Medical Officer or Chief Operating Officer, or their designees, will contact the organization’s leadership to discuss the organization’s accreditation and to offer assistance to the organization in making sustainable improvements.

The organization is required to participate in the Intracyle Monitoring (ICM) process, which means that organizations that were recommended for a PDA at one time will not have the opportunity to merely attest that the organization is in compliance with Joint Commission standards between surveys.

For organizations that had a time-limited PDA, The Joint Commission will schedule the organization’s next unannounced biennial survey early within the 18- to 24-month period.

Should the organization’s next biennial survey result in a repeat Preliminary Denial of Accreditation, the organization will receive a Denial of Accreditation (DA) with the opportunity for an expedited appeal without a hearing.

See Figure 6 for a visual representation of the PDA02 decision process flow.
The Accreditation Process

Figure 6. PDA02 decision process flow.

Process for Organizations That Meet Decision Rule PDA04

If a laboratory does not possess a license, certificate, and/or permit, when required by applicable law and regulation, to provide the health care services for which it is seeking accreditation, Joint Commission staff may initiate the Preliminary Denial of Accreditation process under decision rule PDA04.

The process for Preliminary Denial of Accreditation in such circumstances is as follows:

- If at the time of survey the laboratory does not have a required license, certificate, or permit, the laboratory will be notified that it meets a rule for Preliminary Denial of Accreditation and The Joint Commission will initiate such action.

- The laboratory will also be notified that if it obtains the required license, certificate, or permit or is able to provide proof of application during the clarification process, the PDA decision will be removed but the RFI will remain in the survey report.

- The laboratory will not be presented to executive leadership unless it meets a decision for Preliminary Denial of Accreditation based on another decision rule.
Review and Appeal Procedures

After any Preliminary Denial of Accreditation decision, the organization has the right to ask in writing, within five (5) business days of being notified, for a hearing before a Review Hearing Panel. Failure to appeal results in a Denial of Accreditation.

Organizations that choose to appeal may submit additional materials for the Hearing Panel’s consideration. After the hearing, The Joint Commission reviews the findings of the Review Hearing Panel and either denies accreditation to the organization or selects an appropriate alternative accreditation decision.

The outline in this section details the review and appeal procedures for any accreditation decision.

I. Evaluation by Joint Commission Staff

A. Review and Determination by Joint Commission Staff. Following any survey activity, Joint Commission staff review survey findings, survey documents, and any other relevant materials or information received from any source. Joint Commission staff may take one of the following actions:

- Recommend that the organization be Accredited.
- Recommend that the organization receive Accreditation with Follow-up Survey.
- Recommend that the organization receive Preliminary Denial of Accreditation.
- Defer consideration while additional information regarding the organization’s compliance status is reviewed.
- Determine that the organization be granted Limited, Temporary Accreditation in accordance with the Early Survey Policy.
- Recommend that the organization initially be denied Limited, Temporary Accreditation in accordance with the Early Survey Policy.

B. Determination to Recommend Preliminary Denial of Accreditation. If Joint Commission staff, based on survey findings, survey documents, and any other relevant materials or information received from any source, determine in accordance with approved decision rules to recommend that the organization receive Preliminary Denial of Accreditation, it will outline its findings and determination. The organization may take either of the following actions:

- Accept the findings and determination of the staff through submission of the ESC (or POC, if decision rule PDA02 is applicable).
Submit to The Joint Commission, through the ESC (or POC, if decision rule PDA02 is applicable), any clarification of its compliance with Joint Commission standards at the time of the survey.

Joint Commission staff members review the organization’s submission of any additional information and shall, in accordance with approved decision rules, take one of the following actions:

- Recommend that the organization receive Accreditation with Follow-up Survey.
- Recommend that the organization receive Preliminary Denial of Accreditation.
- Recommend that the organization be Accredited.

C. Immediate Threat to Health or Safety. If the findings of any survey identify a condition that poses a threat to public or patient health or safety, the president of The Joint Commission, or his or her designee, may promptly decide that the organization be immediately placed in Preliminary Denial of Accreditation. This action and the findings that led to this action shall be reported by telephone and in writing to the organization’s chief executive officer and in writing to the authorities having jurisdiction.

II. Accreditation with Follow-up Survey
A. Survey to Determine Implementation of ESC. The Joint Commission conducts a survey of the organization to determine the degree to which deficiencies have been corrected or improvements implemented following a survey any time up to 6 months from the date the organization is notified of its Accreditation with Follow-up Survey decision.

B. Charges to the Organization. The full costs of all surveys shall be borne by the surveyed organization.

III. Review Hearings
A. Right to a Review Hearing. Upon request, an organization that has received a Preliminary Denial of Accreditation (PDA) is entitled to a review hearing. A PDA decision will become a Denial of Accreditation unless the organization makes a timely request for a review hearing to demonstrate why it should not be denied accreditation. If an appeal is requested, the organization remains in PDA status until The Joint Commission renders a final decision.
B. Purpose of the Review Hearing. The review hearing is an opportunity for an organization to present facts and/or arguments to a Review Hearing Panel comprising two outside health care professionals and one member of The Joint Commission’s Board of Commissioners. Presentations are limited to either of the following:

- Facts that were in error during the survey or post-survey processes
- Arguments that The Joint Commission did not follow its policies, procedures, or decision rules

C. Requesting a Review Hearing; Notice of Time and Place. An organization must submit a written request for a review hearing within five (5) business days of The Joint Commission’s notification of the final PDA decision. For the purpose of this section, the date of a notification is the date a notice was posted to the organization’s Joint Commission Connect extranet site. Within a reasonable period of time before the review hearing, The Joint Commission provides notice of the time and date of the review hearing. If the organization intends to submit a written response, or other documents limited to the parameters established above, such response and documents must be submitted at least five (5) business days prior to the review hearing. The Review Hearing Panel is under no obligation to consider late submissions.

D. Charges to the Organization. The organization will be charged a nonrefundable fee for the review hearing, as published in the accreditation and certification pricing schedule found on the Joint Commission Connect extranet site. The fee, along with any other outstanding invoices due to The Joint Commission, must be paid in full at the time an organization requests a review hearing.

E. Procedure for the Conduct of a Review Hearing. Review hearings are limited to three (3) hours. After introductions, Joint Commission staff will summarize the historical facts that led to the PDA decision. The organization will then have an opportunity to make its presentation to the Panel. The organization’s presentation should be limited to factual or procedural errors. The Panel may ask questions of the organization and of Joint Commission staff.

Hearings are not video/audio recorded. The organization may choose to retain a transcriptionist for the hearing at its own expense. The organization shall provide a copy of any transcript to The Joint Commission, at the organization’s expense, at or around the same time the transcript is made available to the organization. Transcripts of Joint Commission proceedings are confidential and shall remain confidential. Any disclosures to a third party require the express written permission of The Joint Commission.
F. Participants at the Review Hearing. A review hearing may proceed with only two of the three panel members present, provided one of the two is a member of the Board. Legal staff from The Joint Commission will be present to address procedural matters and will not ask questions of the organization’s representatives. Organizations are encouraged to limit representatives at the review hearing to individuals who are knowledgeable about the organization in the standards areas found noncompliant. An organization may choose to bring legal counsel and/or consultants; however, this type of representative is permitted to address procedural matters only and is not to speak on matters regarding substantive issues of the organization’s standards compliance or question Joint Commission staff.

G. Report of the Review Hearing. After a review hearing, the Review Hearing Panel will prepare and submit a written report that summarizes its findings on factual matters with a recommendation to The Joint Commission. The panel report may include a recommendation for one of the following accreditation decisions:

1. Denial of Accreditation
2. Time-Limited Preliminary Denial of Accreditation
3. Accreditation with Follow-up Survey
4. Full Accreditation

The Joint Commission shall send the organization a copy of the report approximately ten (10) business days before Joint Commission executive leadership reviews the written report. The organization will have an opportunity to comment on the report within five (5) business days of receipt. The Joint Commission is under no obligation to consider late submissions.

IV. Following a Review Hearing

A. Scope of Review. After the review hearing, The Joint Commission will consider the Review Hearing Panel’s findings and recommendation, the responses of the organization, any newly submitted documents limited to factual and/or procedural errors, and comments of staff, if any, to the Review Hearing Panel’s findings and recommendations.

B. Action by The Joint Commission. After review of the hearing report, The Joint Commission may accept, reject, or modify the Review Hearing Panel’s recommendation.
V. Final Review & Appeal Request

A. Final Review & Appeal Request. An organization that has received Denial of Accreditation or retained a time-limited PDA after having had a hearing is entitled to a Final Review & Appeal to members of The Joint Commission’s Board of Commissioners. The Joint Commission must receive the organization’s request for final review within five (5) business days after the organization receives notice of The Joint Commission’s decision following a hearing.

B. Composition and Participation. No member of the Final Review & Appeal will have participated in the decisions of The Joint Commission to this point but may, when convened for a final review and appeal, ask questions of Joint Commission staff and the Commissioner who served on the Review Hearing Panel, if available. Although the organization does not participate in the final review and appeal proceeding, it may submit a letter to the Board members.

C. Notice of Time and Procedure for Review. The Joint Commission shall provide notice of the date of the Final Review & Appeal meeting prior to the meeting. The organization may submit written comments to the Board members conducting the Final Review & Appeal along with any documents not previously submitted limited to factual or procedural errors made by The Joint Commission. Any documents must be submitted at least five (5) business days prior to the meeting and should specifically identify any relevant documents previously submitted for the purpose of demonstrating its compliance with standards or The Joint Commission’s failure to follow its policies, procedures, or decision rules.

D. Final Action. The Board members conducting the Final Review & Appeal shall review the decision of The Joint Commission, the organization’s responses, any materials specifically identified as relevant by the organization, and other information it deems relevant, and shall take either of the following actions:

- Place the organization in Denial of Accreditation after finding that there is substantial evidence to support The Joint Commission’s decision.
- Make an independent evaluation of The Joint Commission’s decision and then decide to grant Accreditation with Follow-up Survey or full Accreditation to the organization.

The action taken by the Board members conducting the Final Review & Appeal shall be the final accreditation decision of The Joint Commission.
Standards Applicability Grid (SAG)

Not all of the standards/requirements in the CAMLAB apply to all laboratories. Based on the particular services provided by your laboratory, you should use these grids to identify which standards/requirements are applicable.

Services are listed horizontally along the top of the grids. The standard/requirement and element of performance (EP) numbers are listed vertically. Applicability is indicated with an X.

The following services are listed in the laboratory applicability grid (starting on page SAG-3):

- Blood Donor Center
- Chemistry
  - Toxicology/Endocrinology/Routine Chemistry
  - Urinalysis
- Clinical Cytogenetics
  - Clinical Cytogenetics
  - Immunogenetics
- Diagnostic Immunology
- Embryology
- Histocompatibility
- Hematology
  - Andrology
  - Flowcytometry
  - Hematology/Coagulation
- Immunohematology
  - Blood Transfusion
  - All Other Immunohematology
- Microbiology
  - Bacteriology/Mycobacteriology/Mycology
  - Culture Set-up Only
  - Parasitology
Virology

Molecular Biology

Pathology
  - Autopsy Services
  - Cytology (gynecological and nongynecological)
  - Electron Microscopy
  - Histopathology/Oral Pathology/Dermatopathology

Radiobioassay

Provider-Performed Microscopy (PPM)

Tissue Storage

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**Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing**
<p>| Standard/Requirement Number | EP Number | Chemistry | Clinical Cytogenetics | Clinical Cytogenetics | Diagnostic Immunology | Embryology | Hematology | Hematology | Hemohematology | Immunohematology | All Other Immunochemistry | Bacteriology | Mycobacteriology | Culture Setup Only | Pathology | Molecular Biology | Autopsy Services | Cytology | Virology | Provider-Performed Microscopy (PPM) | Tissue Storage | Waived Testing |
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Standard Applicability Grid
Sentinel Events (SE)

I. Sentinel Events
The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help laboratories that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of patient safety events, as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent patient harm. The Sentinel Event Policy explains how The Joint Commission partners with laboratories that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

Definition of Sentinel Event
A sentinel event is a patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in any of the following:
- Death
- Permanent harm
- Severe temporary harm

An event is also considered sentinel if it is one of the following:
- Suicide of any patient receiving care, treatment, or services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, or services

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Sexual abuse/assault (including rape) as a sentinel event, is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the laboratory, including oral, vaginal, or anal penetration or fondling of the patient’s sex organ(s) by another individual’s hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:

- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the laboratory to support allegations of unconsented sexual contact

Invasive procedures, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.

Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.

Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)

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1 Sexual abuse/assault (including rape) as a sentinel event, is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the laboratory, including oral, vaginal, or anal penetration or fondling of the patient’s sex organ(s) by another individual’s hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:

- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the laboratory to support allegations of unconsented sexual contact

2 Invasive procedures, including surgery, on the wrong patient, at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

3 “After surgery” is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
- Any intrapartum (related to the birth process) maternal death
- Severe maternal morbidity (not primarily related to the natural course of the patient’s illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm

The above list is consistent across all Joint Commission accreditation programs, though some of these events may be unlikely to occur in certain settings. When the laboratory is uncertain that a patient safety event is a sentinel event as defined by The Joint Commission, the event will be presumed to be a patient safety event and not a sentinel event unless determined otherwise through further investigation or the presentation of relevant information. Patient safety events require analysis and should be shared with the Office of Quality and Patient Safety through an organization response.

All sentinel events must be reviewed by the laboratory, and are subject to review by The Joint Commission. Accredited laboratories are expected to identify and respond appropriately to all sentinel events (as defined by The Joint Commission) occurring in the laboratory or associated with services that the laboratory provides. An appropriate response includes all of the following:

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\(^{3}\) Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association. *NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data.* Quincy, MA: NFPA, 2011.

\(^{4}\) Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of 4 or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU). *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk—and timely implementation of clinical interventions consistent with evidence-based guidelines—are important steps in the ongoing provision of safe and reliable care. Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings. For additional details, see “Update: Revised Definition of Severe Maternal Morbidity in Sentinel Event Policy,” June 2015 Perspectives.
A formalized team response that stabilizes the patient, discloses the event to the patient and family, and provides support for the family as well as staff involved in the event

- Notification of laboratory leadership
- Immediate investigation
- Completion of a comprehensive systematic analysis for identifying the causal and contributory factors
- Strong corrective actions derived from the identified causal and contributing factors that eliminate or control system hazards or vulnerabilities and result in sustainable improvement over time
- Time line for implementation of corrective actions
- Systemic improvement

Sentinel events are one category of patient safety events. A patient safety event is an event, incident, or condition that could have resulted or did result in harm to a patient. A patient safety event can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error. Patient safety events also include adverse events, no-harm events, close calls, and hazardous conditions, which are defined as follows:

- An adverse event is a patient safety event that resulted in harm to a patient.
- A no-harm event is a patient safety event that reaches the patient but does not cause harm.
- A close call (or “good catch”) is a patient safety event that did not reach the patient.
- A hazardous (or “unsafe”) condition(s) is a circumstance (other than a patient’s own disease, process, or condition) that increases the probability of an adverse event.

The laboratory determines how it will respond to patient safety events that do not meet the Joint Commission’s definition of sentinel event. Adverse events shall prompt notification of laboratory leaders, investigation, and corrective actions, in accordance with the laboratory’s process for responding to patient safety events that do not meet the definition of sentinel event. An adverse event may or may not result from an error.

No harm events, close calls, and hazardous conditions are tracked and used as opportunities to prevent harm, in accordance with the laboratory’s process for responding to patient safety events that do not meet the definition of sentinel event.
II. Goals of the Sentinel Event Policy
The policy has the following four goals:
1. To have a positive impact in improving patient care, treatment, and services and in preventing unintended harm
2. To focus the attention of a laboratory that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or laboratory culture), and on changing the laboratory’s culture, systems, and processes to reduce the probability of such an event in the future
3. To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention
4. To maintain the confidence of the public, clinicians, and laboratories that patient safety is a priority in accredited laboratories.

III. Responding to Sentinel Events

Standards
Each Joint Commission accreditation manual contains standards that relate specifically to the management of sentinel events. (See the Appendix to this chapter for related standards.)

Standard **LD.04.04.05**, element of performance (EP) 7, requires each accredited laboratory to define patient safety event and to communicate this definition throughout the laboratory. This definition must encompass sentinel events as defined by The Joint Commission. An accredited laboratory is encouraged to include in its definition events, incidents, and conditions in which no or only minor harm occurred to a patient. The laboratory determines how it will respond to patient safety events that do not meet the definition of sentinel event.

Comprehensive Systematic Analysis
As indicated above, appropriate response to a sentinel event includes the completion of a comprehensive systematic analysis for identifying the causal and contributory factors. Root cause analysis, which focuses on systems and processes, is the most commonly used form of comprehensive systematic analysis used to identify the factors that underlie a sentinel event.
A laboratory may use other tools and methodologies to conduct its comprehensive systematic analysis. The Joint Commission encourages the laboratory to contact the patient safety specialist assigned to the laboratory’s event or to call the Office of Quality and Patient Safety at 630-792-3700 if it has questions regarding using the tools discussed above or other tools it is considering. (See the “Review of Comprehensive Systematic Analyses and Corrective Action Plans” section for further discussion of acceptability.)

**Corrective Action Plan**

The product of the comprehensive systematic analysis is a corrective action plan. The corrective action plan identifies the strategies that the laboratory intends to implement in order to reduce the risk of similar events occurring in the future. The identified actions should eliminate or control system hazards or vulnerabilities that have been identified by the comprehensive systematic analysis. Analysis teams should identify at least one stronger or intermediate strength action when possible (see Figure 3 on page 17 of the National Patient Safety Foundation [NPSF] *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm* report at http://c.ymcdn.com/sites/www.npsf.org/resmgr/PDF/RCA2_v2-online-pub_010816.pdf for more information on strength of action). The plan must address the following:

- Identification of corrective actions to eliminate or control system hazards or vulnerabilities directly related to causal and contributory factors
- Responsibility for implementation
- Time lines for completion
- Strategies for evaluating the effectiveness of the actions
- Strategies for sustaining the change

**Reporting a Sentinel Event to The Joint Commission**

Each laboratory is strongly encouraged, but not required, to report to The Joint Commission any patient safety event that meets the Joint Commission definition of sentinel event. A laboratory benefits from self-reporting in the following ways:

- The Joint Commission can provide support and expertise to the laboratory during the review of a sentinel event.
A review with the Office of Quality and Patient Safety provides the opportunity for the laboratory to collaborate with a patient safety specialist who is likely to have reviewed similar events.

Reporting raises the level of transparency in the laboratory and helps promote a culture of safety.

Reporting conveys the laboratory’s message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future.

Further, reporting the event enables the addition of the “lessons learned” from the event to be added to The Joint Commission’s Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events in many other laboratories.

The value of this review is reflected by the fact that more than 75% of sentinel events reported to The Joint Commission are self-reported by the organizations that experienced the events. Alternatively, The Joint Commission may become aware of a sentinel event by some other means such as communication from a patient, a family member, an employee of the laboratory, a surveyor, or through the media.

Self-reporting a sentinel event is not required and there is no difference in the expected response, time frames, or review procedures, whether the laboratory voluntarily reports the event or The Joint Commission becomes aware of the event by some other means. If a laboratory wishes to report to The Joint Commission an occurrence of a sentinel event, the laboratory will be asked to complete a form accessible through its Joint Commission Connect™ extranet site. From this site, place the cursor over “Continuous Compliance Tools.” A dropdown list will appear. From this list, select “Self Report Sentinel Event.”

If The Joint Commission becomes aware of a sentinel event that was not reported by the laboratory to The Joint Commission, the CEO (or designee) of the laboratory is contacted, and a preliminary assessment of the sentinel event is made. An event that occurred more than one year before the date The Joint Commission became aware of the event will not, in most cases, be reviewed under the Sentinel Event Policy. In such a case, a written response will be requested from the laboratory, including a summary of the processes that were designed to prevent similar occurrences.
Required Response to a Sentinel Event
All sentinel events must be reviewed by the laboratory, whether or not they are reported to The Joint Commission. In addition, if The Joint Commission becomes aware (either through voluntary self-reporting or otherwise) of a sentinel event that meets the criteria of this policy and the event has occurred in an accredited laboratory, the laboratory is expected to do the following:

- Prepare a thorough and credible comprehensive systematic analysis and corrective action plan within 45 business days of the event or of becoming aware of the event.
- Submit to The Joint Commission its comprehensive systematic analysis and corrective action plan, or otherwise provide for Joint Commission evaluation its response to the sentinel event using an approved methodology within 45 business days of the known occurrence of the event. The Joint Commission will determine whether the comprehensive systematic analysis and corrective action plan are acceptable.

The fact that a laboratory has experienced a sentinel event will not impact its accreditation decision. However, willful failure to respond appropriately to the sentinel event could have such an impact. For instance, if the laboratory fails to submit a comprehensive systematic analysis within an additional 45 days following its due date, its accreditation decision may be impacted. In these instances, patient safety specialists in the Office of Quality and Patient Safety, along with the medical director and patient safety officer, would recommend the chief medical officer and the executive leadership of The Joint Commission change the laboratory’s accreditation status.

Submission of Comprehensive Systematic Analyses and Corrective Action Plans
A laboratory that reports sentinel event must submit the comprehensive systematic analysis, including the resulting corrective action plan that describes the laboratory’s risk reduction strategies as well as how the effectiveness of those strategies will be evaluated. This information is submitted electronically and will be reviewed in a conference call involving Joint Commission staff and laboratory staff (Alternative–0). Documents shall not include the names of caregivers and patients involved in the sentinel event.

If the laboratory has concerns about waiving confidentiality protections as a result of sending the comprehensive systematic analysis documents to The Joint Commission, the following four optional alternative approaches to a review of the laboratory’s response to the sentinel event are acceptable:
1. A review of the comprehensive systematic analysis and corrective action plan documents brought to Joint Commission headquarters by laboratory staff, then taken back to the laboratory on the same day (Alternative–1). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative). When the web-based video conference is used, the laboratory’s participants remain at the laboratory.

2. An on-site meeting at the laboratory with a Joint Commission patient safety specialist to review the comprehensive systematic analysis and corrective action plan (Alternative–2). This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).

3. An on-site review with a Joint Commission patient safety specialist to review the corrective action plan and relevant documentation (Alternative–3). The patient safety specialist may ask questions regarding the comprehensive systematic analysis, but will not review that document itself. For purposes of this review activity, relevant documentation includes, at a minimum, any documentation relevant to the laboratory’s process for responding to sentinel events and the corrective action plan resulting from the analysis of the sentinel event. The corrective action plan serves as the basis for determining appropriate follow-up activity. This can also be performed via web-based video conferencing with a patient safety specialist who is located at The Joint Commission (Web-Alternative).

4. An on-site visit by a specially trained surveyor arranged to conduct the following (Alternative–4):
   a. Interview and review of relevant documentation, including, if applicable, the patient’s medical record, to evaluate the following:
      ■ The process the laboratory uses in responding to sentinel events
      ■ The relevant policies and procedures preceding and following the laboratory’s review of the specific event, and the implementation thereof, sufficient to permit inferences about the adequacy of the laboratory’s response to the sentinel event
   b. A standards-based survey that traces a patient’s care, treatment, and services and the laboratory management functions relevant to the sentinel event under review

Each of these options will result in a fee to the laboratory to cover the average direct costs of the option. Inquiries about the fee should be directed to the Joint Commission’s Pricing Unit at 630-792-5115.
**Review of Comprehensive Systematic Analyses and Corrective Action Plans**

A comprehensive systematic analysis will be reviewed for thoroughness, credibility, and acceptability. A laboratory’s comprehensive systematic analysis should identify system vulnerabilities so that they can be eliminated or mitigated. The analysis should not focus on individual health care worker performance, but should seek out underlying systems-level causations that were manifest in personnel-related performance issues. To help adhere to these characteristics it is recommended but not required that the following guidelines be considered when developing causative factor statements:

- Clearly show the cause-and-effect relationship.
- Use specific and accurate descriptors for what occurred, rather than negative and vague words.
- Human errors must have a preceding cause.
- Violations of procedure are not root causes, but must have a preceding cause.
- Failure to act is only causal when there is a preexisting duty to act.

To be thorough, the comprehensive systematic analysis must include the following:

- The analysis repeatedly asks a series of “Why” questions, until it identifies the systemic causal factors associated with each step in the sequence that led to the sentinel event
- The analysis focuses on systems and processes, not solely on individual performance
- A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence
- The analysis of the underlying systems and processes through the series of “Why” questions determines where redesign might reduce risk
- An inquiry into all areas appropriate to the specific type of event

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An identification of risk points and their potential contributions to this type of event

A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist

To be credible, the comprehensive systematic analysis must do the following:

- Include participation by a process owner, who is not a member of the response team; typically this is a senior leader of the laboratory or a designee‡‡
- Each action recommended by a review team should be approved or disapproved, preferably by the CEO or alternatively by another relevant member of top management. If an action is disapproved, the reason for its disapproval should be shared with the comprehensive systematic analysis and action team so that the constraint can be understood and another developed by the team to replace it if the system vulnerability is not otherwise effectively addressed in the corrective action plan.§§
- Include patients, family, or patient representatives when appropriate to ensure a thorough understanding of the facts.
- Include individuals most closely involved in the processes and systems under review
- Be internally consistent (that is, not contradict itself or leave obvious questions unanswered)
- Provide an explanation for all findings of “not applicable” or “no problem”
- Include a bibliography of any relevant literature

A corrective action plan will be considered acceptable if it does the following:

- Identifies and implements actions to eliminate or control systems hazards or vulnerabilities
- It is recommended but not required that review teams should attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible, reduce the severity or consequences if it should recur.

‡‡ A senior leader is not necessarily required to be actively involved in the day-to-day work of the comprehensive systematic analysis team. However, the team should report to the senior leader or designee, and he or she should be involved in deciding or approving the actions the laboratory will take as a result of the comprehensive systematic analysis.

It is recommended that the review team use a tool that will assist in identifying stronger actions that provide effective and sustained system improvement. A tool such as the Action Hierarchy can help organizations evaluate the strength of the corrective actions identified in their comprehensive systematic analysis. The US Department of Veterans Affairs National Center for Patient Safety developed this tool in 2001. It is recommended that the review team use a tool that will assist in identifying stronger actions that provide effective and sustained system improvement. A tool such as the Action Hierarchy can help organizations evaluate the strength of the corrective actions identified in their comprehensive systematic analysis. The US Department of Veterans Affairs National Center for Patient Safety developed this tool in 2001.

Identifies, in situations in which improvement actions are planned, who is responsible for implementation, when the action will be implemented, how the effectiveness of the actions will be evaluated, and how the actions will be sustained.

Identifies at least one stronger or intermediate strength action for each comprehensive systematic analysis.

All comprehensive systematic analyses and corrective action plans will be considered and treated as confidential by The Joint Commission.

**Follow-up Activities**

After The Joint Commission has determined that a laboratory has conducted an acceptable comprehensive systematic analysis (for example, root cause analysis) and developed an acceptable corrective action plan, The Joint Commission will notify the laboratory that the comprehensive systematic analysis and corrective action plan are acceptable and will assign an appropriate follow-up activity. This will be a mutually agreed-upon documentation of sustained improvement and reduction of risk, which may include one or more sentinel event Measure(s) of Success (SE MOS).

**IV. The Sentinel Event Database**

The third goal of the Sentinel Event Policy is to increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention. To achieve this, The Joint Commission collects and analyzes data from the review of sentinel events, and their comprehensive systematic analyses, corrective action plans, and follow-up activities. These data and information comprise the content of the Joint Commission’s Sentinel Event Database.

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The Sentinel Event Database is also a major component of the evidence base for developing and maintaining the Joint Commission’s National Patient Safety Goals. The database also informs the development prevention advice to laboratories through Sentinel Event Alert or other media. For these purposes, The Joint Commission uses de-identified aggregate data relating to root causes, contributing factors, and risk-reduction strategies. The Joint Commission is committed to developing and maintaining this Sentinel Event Database in a fashion that will protect the confidentiality of the laboratory, the caregiver, and the patient.

V. Determination That a Sentinel Event Is Subject to Review
Based on available information received about the event, a patient safety specialist from the Office of Quality and Patient Safety (OQPS) will determine whether an event meets the definition in Section I, and is therefore a sentinel event. Challenges to a determination that an event is a sentinel event will be resolved through discussions between senior Joint Commission staff and senior laboratory leaders.

VI. Optional On-Site Review of a Sentinel Event
An initial on-site review of a sentinel event will usually not be conducted unless it is determined that a potential ongoing Immediate Threat to Health or Safety exists. An Immediate Threat to Health or Safety is a threat that represents the most immediate risk and has or may potentially have serious adverse effects on the health or safety of patients. All potential Immediate Threats to Health or Safety are referred to Joint Commission executive leadership for authorization to conduct an unannounced on-site for-cause survey. If an on-site survey is conducted, the laboratory will be billed a sufficient charge, based on an established fee schedule, to cover the costs of conducting such a survey.

VII. Disclosable Information
If The Joint Commission receives an inquiry about the accreditation decision of a laboratory that has experienced a sentinel event, the laboratory’s current accreditation status will be reported in the usual manner without making reference to the sentinel
event. If the inquirer specifically references the particular sentinel event, The Joint Commission will acknowledge that it is aware of the event and currently is working or has worked with the laboratory through the sentinel event review process.

VIII. The Joint Commission’s Response

Patient safety specialists from The Joint Commission assess the acceptability of the laboratory’s response to the sentinel event, including the thoroughness and credibility of any comprehensive systematic analysis information reviewed and the laboratory’s corrective action plan. (Root cause analysis is the most commonly used method of comprehensive systematic analysis.) If the comprehensive systematic analysis and corrective action plan are found to be thorough and credible, patient safety specialists from The Joint Commission will notify the laboratory and assign one or more or other mutually agreed-upon documentation of sustained improvement and reduction of risk, such as SE MOS. (See the “Sentinel Event Measures of Success [SE MOS]” section below for more details.)

A patient safety specialist from The Joint Commission will provide consultation to the laboratory if the response is unacceptable, and will allow an additional 15 business days beyond the original submission period for the laboratory to resubmit its response. If the response is still unacceptable, the laboratory’s accreditation decision may be impacted.

IX. Sentinel Event Measures of Success (SE MOS)

The laboratory’s follow-up activity may be conducted through the SE MOS process. SE MOS is a numerical or quantifiable measure, ideally with a numerator and denominator, that indicates whether a planned action was effective and sustained. The SE MOS is due on a mutually agreed-upon date.

If an SE MOS is used, then the following information would apply:

- If an SE MOS is submitted on time but does not meet pre-established levels of compliance, the patient safety specialist from The Joint Commission will request an additional four months of data. If the second set of data does not meet pre-established levels of compliance, the laboratory’s accreditation decision may be impacted.
- If submission of an SE MOS is 90 or more days late, the laboratory’s accreditation status may be impacted.
X. Handling Sentinel Event–Related Documents
Handling of any submitted comprehensive systematic analysis and corrective action plan is restricted to specially trained staff in accordance with procedures designed to protect the confidentiality of the documents.

At the time the review of the de-identified comprehensive systematic analysis is entered into the Sentinel Events Database, the original documents will be destroyed, as well as any copies. However, upon request the original documents may be returned to the laboratory. The information contained in any electronically submitted comprehensive systematic analysis tool will be de-identified after the review is completed.

The corrective action plan resulting from the analysis of the sentinel event will initially be retained long enough to serve as the basis for appropriate follow-up activities, such as the SE MOS or other mutually agreed-upon documentation of sustained improvement. After the corrective action plan has been implemented and meets the established levels of compliance, The Joint Commission will destroy and delete the corrective action plan. If the SE MOS was submitted electronically, the information will likewise be de-identified upon completion of the review.

XI. Oversight of the Sentinel Event Policy
The executive leadership of The Joint Commission is responsible for approval of this policy and overseeing its implementation. In addition to reviewing and deciding individual cases involving changes in a laboratory’s accreditation decision, Joint Commission staff will periodically audit the comprehensive systematic analysis and documentation of follow-up activities. For the purposes of these audits, The Joint Commission temporarily retains random de-identified samples of these documents. Upon completion of the audit, these documents are also destroyed.

For more information about the Joint Commission’s Sentinel Event Policy, visit the Joint Commission’s website at http://www.jointcommission.org or call the Office of Quality and Patient Safety at 630-792-3700.
XII. Survey Process
When conducting an accreditation survey, The Joint Commission seeks to evaluate the laboratory’s compliance with the applicable standards, National Patient Safety Goals, and Accreditation Participation Requirements, and to assess the laboratory’s performance based on those requirements. Surveyors are instructed not to search for or investigate sentinel events during an accreditation survey or to inquire about sentinel events that have been reported to The Joint Commission. However, surveyors may assess a laboratory’s performance improvement practices, such as its processes for responding to a sentinel event.

If, in the course of conducting any survey activities, a potential serious patient safety event is newly identified, the surveyor will take the following steps:
- Inform the laboratory CEO that the event has been identified
- Inform the CEO the event will be reported to The Joint Commission for further review and follow-up under the provisions of the Sentinel Event Policy

Surveyors are not authorized to review the comprehensive systematic analysis documents and determine credibility, thoroughness, or acceptability because they are limited to applying the related standards and elements of performance to assess performance improvement practices, such as processes for responding to safety events, adverse events, hazardous unsafe conditions, close calls, and sentinel events.

The surveyor makes no determination of whether or not the event is a sentinel event and does not focus on or explore the event further, but rather will hand off further discussion to a patient safety specialist in the Office of Quality and Patient Safety. Surveyors are not authorized to investigate sentinel events. The patient safety specialist will contact the laboratory after all survey activity is entirely completed to explore the event and determine whether or not submission of a comprehensive systematic analysis is required. If so, the laboratory will proceed with the steps described after an event is determined to be a sentinel event. (See the “Required Response to a Sentinel Event” section in this chapter.)

During the on-site survey, the surveyor(s) will assess the laboratory’s compliance with sentinel event–related standards in the following ways (see Standard LD.04.04.05 in the Appendix):
- Review the laboratory’s process for responding to a sentinel event
- Interview the laboratory’s leaders and staff about their expectations and responsibilities for identifying, reporting on, and responding to sentinel events
Appendix. Accreditation Requirements Related to Sentinel Events
The following standard and associated elements of performance (EPs) are related to sentinel events:

**Leadership (LD)**

**Standard LD.04.04.05**
The laboratory manages safety issues.

**Elements of Performance for LD.04.04.05**

6. The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. *(See also LD.03.04.01, EP 5; LD.04.04.03, EP 5)*

**Note:** This EP is intended to minimize staff reluctance to report errors in order to help an organization understand the source and results of system and process failures. The EP does not conflict with holding individuals accountable for their blameworthy errors.

7. The leaders define patient safety event and communicate this definition throughout the organization.

**Note:** At a minimum, the organization’s definition includes those events subject to review in the “Sentinel Events” (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a close call or near miss.

8. The laboratory conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the “Sentinel Events” (SE) chapter of this manual.

11. To improve safety, the laboratory analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. *(See also LD.04.04.03, EP 5)*
The Joint Commission Quality Report (QR)

Introduction
The Joint Commission Quality Report differentiates health care organizations based on accreditation decision categories and other related information. While the accreditation decision reflects the process for assessing an organization’s commitment to achieving continuous improvement in key areas of safety and quality, the Quality Report also reflects information about a laboratory’s performance on National Patient Safety Goals, as well as special recognitions and achievements.

This chapter provides an overview of Quality Reports—what they are, how and when they are developed, how organizations can respond to them, and how the public and organizations can access and use them.

For the purpose of readability and ease of use, this chapter is organized in a question-and-answer format. The chapter includes information on the following:
- A description of the Quality Report and the information it contains
- A description of The Joint Commission’s Quality Check® website and its special features
- Guidelines for submitting a commentary
- Marketing and communication guidelines for using Quality Reports

What Is The Joint Commission Quality Report?
The Joint Commission Quality Report provides accreditation information about the laboratory. The Joint Commission provides Quality Reports to surveyed laboratories and makes them available to the public on The Joint Commission’s Quality Check website.
What Will My Quality Report Contain?
The Quality Report features two major components.

**Summary of Quality Information.** This section provides the following information:
- *Accreditation decision*, including the effective date of the decision. This portion also identifies any additional programs in the organization that are accredited by The Joint Commission, if applicable.

**Quality Indicators.** Quality Indicators include National Patient Safety Goals, which are a series of specified actions that accredited organizations are expected to take in order to prevent medical errors. All organizations providing the related relevant services are required to comply with the National Patient Safety Goals. See Figure 1 for the legend of National Patient Safety Goal Quality Indicator symbols.

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*Figure 1. Legend of National Patient Safety Goal Quality Indicator Symbols*

What Is Quality Check?
Quality Check is a directory of the more than 20,000 Joint Commission–accredited and certified health care organizations and programs throughout the United States. You can access Quality Check at http://www.qualitycheck.org.

These features are included on Quality Check:
- Enhanced search functionality that allows the user to search for a health care organization by the following criteria:
  - Joint Commission–assigned organization number (HCO ID)
  - City, state, or zip code
- Type of service provided
- Accreditation or Certification program—This includes certified programs, home care providers, hospitals, laboratories, behavioral health care organizations, nursing care centers, office-based surgery practices, and ambulatory care organizations
- Organization name—This includes Legal Business Name, as well as Doing Business As (DBA) Name (the DBA may be what consumers are most likely to know)

A search results page that displays any organization that matched the user’s search criteria. Also included on this page are filter options, which allow the user to narrow search results by state, services, deemed or CMS–recognition programs, accreditation or certification programs.

**Is a Quality Report Available for My Accredited Laboratory?**

Yes. The amount of information available on the report depends on the type of laboratory surveyed. A complete directory of all Joint Commission–accredited organizations is available through Quality Check’s website (http://www.qualitycheck.org).

Historical Quality Reports (when applicable) can also be accessed on Quality Check. The Joint Commission’s Customer Service Department (630-792-5800) can also address queries about Quality Report availability for an organization and can provide lists of all available reports.

**Can My Laboratory Comment on Its Quality Report?**

Yes. The Joint Commission offers each laboratory the opportunity to provide its perspective on its Quality Report commentary. Your laboratory has the option of submitting a commentary of up to two pages. Submission of the commentary is voluntary.
How Does My Laboratory Submit a Commentary?

If your laboratory chooses to submit a commentary, it may do so by completing an online form that is accessed through your organization’s secure Joint Commission Connect™ extranet site. After your laboratory submits the form, Joint Commission staff will review the submitted commentary for appropriateness, and then “Accept” the document for posting with the Quality Report on Quality Check. If the submitted commentary does not meet appropriateness guidelines, Joint Commission staff will notify your organization and allow you to resubmit a revised and approved copy.

Are There Any Criteria That Must Be Met in a Commentary?

The commentary must meet the following criteria:

- Only one commentary is permitted per laboratory, regardless of the number of the laboratory’s accredited services evaluated in a survey.
- The commentary is limited to a maximum of two pages.
- The commentary does not mention surveyors by name or use defamatory or libelous language.

The commentary may be updated at any time by submitting a revised commentary through your laboratory’s Joint Commission Connect site.

What Are the Marketing and Communication Guidelines for Using Quality Reports?

The Joint Commission recognizes your laboratory’s right to communicate your accreditation decision to interested individuals. Indeed, many laboratories across the country point with pride to Joint Commission accreditation as a “seal of approval” of their efforts to provide high-quality services. In fact, The Joint Commission offers a Gold Seal of Approval™ for health care organizations to use to publicize their accreditation. Guidelines for use of the Gold Seal are available on The Joint Commission’s website (http://www.jointcommission.org/accreditation/gold-seal_downloads.aspx).

However, your laboratory must also communicate responsibly. An organization accredited by The Joint Commission must be accurate when describing to the public the nature and meaning of its accreditation including the public use of its Quality Report. A
laboratory may not engage in any false or misleading advertising with respect to the accreditation award. Any such advertising may be grounds for denying or revoking accreditation (see APR.08.01.01 in the “Accreditation Participation Requirements” [APR] chapter).

**Guidelines for Publicizing Joint Commission Accreditation**

The Joint Commission requires that an accredited laboratory accurately describe to the public the nature and meaning of its accreditation and its decision award. Any accredited laboratory that materially misleads the public about any matter relating to its accreditation may have to undertake appropriate corrective advertising or risk loss of accreditation.

Guidelines for publicizing accreditation include the following:

- If your laboratory has sites or offers services that are not accredited, any reference to accreditation must clearly specify which sites/services are accredited. For example, if you are an organization with multiple service components, such as a hospital with a laboratory component, and The Joint Commission did NOT review your laboratory component, you must insert the following language into your materials: “This award excludes laboratory services.”

- Accreditation does not “endorse” or “guarantee” a laboratory’s quality or safety of care; nor does it “prove,” “assure,” or “testify” that an organization provides high-quality, safe care. Such language should not be used in your materials.

- Correctly state the laboratory’s accreditation accomplishment. To say that your laboratory is the “first” or the “only” laboratory in the area to receive accreditation or a specific accreditation designation may not be true and can be misleading.

- When referring to The Joint Commission, use the name “The Joint Commission.”

For further information on publicizing your accreditation or using the Gold Seal of Approval, laboratories may contact The Joint Commission’s Corporate Marketing Department by visiting our website at https://www.jointcommission.org/accreditation/celebrating_your_accreditation.aspx, or see the “Award Display and Use” section in “The Accreditation Process” (ACC) chapter.
Guidelines for Publicizing the National Patient Safety Goals®

The Joint Commission established the National Patient Safety Goals in 2002 to help accredited organizations prevent specific medical errors from occurring, such as patient misidentification and medication errors. All Joint Commission–accredited health care organizations are surveyed for compliance with the requirements of the goals—or acceptable alternatives—as appropriate to the services the organization provides. The Joint Commission develops program–specific goals for each of its accreditation and certification programs.

Guidelines for publicizing your laboratory’s compliance with the National Patient Safety Goals include the following:

- You may state that your laboratory is in compliance with the goals but you must state when that was validated. For example, “We were last surveyed for compliance with the National Patient Safety Goals in 2016,” or “Our compliance with the National Patient Safety Goals was validated by The Joint Commission in 2017.”

- Your laboratory must be in compliance with all applicable goals in order to receive a “check mark” on the summary page of your Quality Report. Tell your patients to “look for the check mark” when evaluating health care providers.

- If your laboratory fails to comply with one or more of the goal requirements and receives a “minus symbol” on its Quality Report summary page, you may still publicize your compliance but only with the goals and requirements with which you comply. In this instance, you may not imply compliance with all applicable goals.

For more information, please visit our website: https://www.jointcommission.org/accreditation/guidelines_for_publicizing_npsg_compliance.aspx.
Required Written Documentation (RWD)

This chapter provides you with a list of elements of performance (EPs) that require written documentation. You may find it useful to use this document as a checklist to maintain continuous compliance with the requirements.

The Joint Commission’s focus is on performance and implementation rather than documentation. The standards, consequently, require documentation only when it is essential. The documentation icon——is used to identify data collection and documentation requirements that are in addition to information found in the patient’s clinical record. For example, the documentation icon is applied to an EP that requires a written procedure, but the icon is not applied to an EP that lists the required components of the patient’s clinical record. Other examples in which the documentation icon is applied are EPs that require a policy, a written plan, a Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate, a license, evidence of testing, documentation of reviews by laboratory supervisors and directors, data, lists, performance improvement reports, specimen identification and labels, Material Safety Data Sheets, and meeting minutes. The documentation icon is applied to EPs in the “Document and Process Control” (DC) chapter that describe information in laboratory reports because these reports are retained with the laboratory as well as filed in the clinical record of the patient. Documentation can be on paper or in an electronic format.

While documentation is important, the primary emphasis of the survey will be on how your laboratory carries out the functions described in the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB). The surveyors may use a combination of data sources, including interviews with leaders of the laboratory, staff, patients, and patient family members; visits to patient care settings; and review of documentation to arrive at an assessment of the laboratory’s compliance with a standard.

Note: This list is meant to be a guide for you in preparing for the survey. The names and format of specific documents may vary from laboratory to laboratory.
## List of EPs Requiring Written Documentation for Laboratories and Point-of-Care Testing

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</table>
Early Survey Policy (ESP)

A laboratory seeking accreditation for the first time by The Joint Commission may choose the Early Survey Policy option. The laboratory must declare during the application process that it wishes to pursue this option. Under this option, a laboratory must undergo two surveys. The first survey, which is announced, would cover a limited selection of standards. The second survey, which is also announced, would be a full survey.

For a detailed explanation of the Early Survey Policy, please see “The Accreditation Process” (ACC) chapter in this manual.

This following table lists the selected elements of performance (EPs) and requirements that are applicable to a first survey when a laboratory has chosen the Early Survey Policy option.

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### Environment of Care (EC)

| EC.01.01.01, EPs 1, 4-9 | EC.02.04.05, EPs 1-4 |
| EC.02.01.01, EPs 1, 3, 5, 7, 8, 11, 12 | EC.02.05.01, EPs 3-5, 7-13 |
| EC.02.01.03, EP 1 | EC.02.05.03, EPs 1-3, 5, 8-10 |
| EC.02.02.01, EPs 1, 3-7, 9-12 | EC.02.05.05, EP 1, 5, 8 |
| EC.02.03.01, EPs 1, 3, 4, 9, 10, 13 | EC.02.05.07, EPs 1, 4, 6 |
| EC.02.03.03, EPs 2, 5 | EC.02.06.01, EPs 13, 28-32, 37 |
| EC.02.03.05, EPs 15, 21, 24 | EC.02.06.05, EPs 1, 5 |
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| EC.02.04.03, EPs 4, 6, 7, 9, 11-14, 17, 27 | EC.04.01.01, EPs 1, 3-6, 8-11 |
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### Emergency Management (EM)

| EM.01.01.01, EP 1 | EM.02.02.07, EPs 2-4 |
| EM.02.01.01, EPs 1, 2, 4-6 | EM.02.02.09, EP 1 |
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| EM.02.02.03, EPs 2, 3 | EM.02.02.15, EPs 2-4 |
| EM.02.02.05, EP 1 |  |

### Human Resources (HR)

| HR.01.01.01, EPs 2, 3, 6 | HR.01.04.01, EPs 1, 3, 9, 10 |
| HR.01.02.03, EPs 1-9 | HR.01.05.03, EPs 1, 5 |
| HR.01.02.05, EP 1 | HR.01.06.01, EPs 3, 5, 6, 15, 18, 21, 22 |
| HR.01.02.07, EPs 1, 2 | HR.01.07.01, EPs 1, 2, 5 |
| HR.01.03.01, EP 3 |  |

### Infection Prevention and Control (IC)

<p>| IC.01.01.01, EP 3 | IC.02.01.01, EPs 1-3, 6-9 |
| IC.01.02.01, EPs 1, 3 | IC.02.02.01, EPs 1-4 |
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## Quality System Assessment for Nonwaived Testing (QSA)

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### Transplant Safety (TS)

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### Waived Testing (WT)

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Appendix A: Retention Times for Records, Reports, and Specimens (AXA)

Retention Times for Records, Reports, and Specimens
The minimum required retention times for various records, reports, and specimens are listed below. In instances where state or local regulations require longer retention periods, the laboratory must conform to those.

Note: When a laboratory ceases operation, the laboratory must make provisions to ensure that all records, slides, blocks, and tissue are maintained and available for the time frames specified in law and regulation.

<table>
<thead>
<tr>
<th>Item</th>
<th>Retention Times</th>
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</table>
| Equipment records           | 2 years—daily, weekly, or monthly performance testing and function checks  
Life of the equipment—major repairs, parts replacement, and annual maintenance |
| Test requisitions           | 2 years                                              |
| Records of testing          | 10 years—immunohematology                            
5 years—histocompatibility  
2 years—all others           |
| Test report (preliminary and final) | 10 years—immunohematology  
10 years—histology and cytology and bone marrow  
25 years (suggested)—cytogenetic  
2 years—all others          |
<table>
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<th>Item</th>
<th>Retention Times</th>
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<tr>
<td>Proficiency testing</td>
<td>2 years—records of test handling, preparation, processing, examination, results of reporting, the signed attestation statement, and feedback reports (Note: 5 years recommended but not required to support proficiency testing monitoring activities)</td>
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<tr>
<td>Quality control</td>
<td>5 years—immunohematology, histocompatibility, and tissue banking</td>
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<tr>
<td></td>
<td>2 years—all others</td>
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<tr>
<td>Instrument printouts</td>
<td>CLIA ’88 requires printouts to be retained at least 2 years, unless the record data are retrievable in an alternate manner</td>
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<tr>
<td>Discontinued procedures</td>
<td>5 years—immunohematology and tissue banking</td>
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<tr>
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<td>2 years—all others</td>
</tr>
<tr>
<td>Histology</td>
<td>7 days after reporting—gross specimens</td>
</tr>
<tr>
<td></td>
<td>10 years—slides and images</td>
</tr>
<tr>
<td></td>
<td>2 years from examination date—blocks</td>
</tr>
<tr>
<td>Cytology</td>
<td>5 years from examination date or as required by state law—slides</td>
</tr>
<tr>
<td></td>
<td>10 years—fine needle aspiration slides</td>
</tr>
<tr>
<td>Tissue records</td>
<td>10 years—records showing tissue supplier, the original numeric or alphanumeric donor or lot identification, names(s) of the recipients(s) or other final dispositions of each tissue and expiration of all tissues</td>
</tr>
<tr>
<td>Item</td>
<td>Retention Times</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Blood bank records</td>
<td>Indefinite retention—testing records for blood donors who are permanently deferred&lt;br&gt;7 days post-transfusion and 10 days post post-crossmatch—samples of transfused blood and a sample of recipient blood&lt;br&gt;5 years—documentation of testing of blood and blood components&lt;br&gt;10 years—audit trail detailing the receipt and disposition of all blood and blood components&lt;br&gt;10 years—identification of the recipient for blood and blood components issued by the facility that collected and processed the unit</td>
</tr>
<tr>
<td>Embryo laboratory records</td>
<td>As specified by law or 10 years beyond the date of final disposition or disposal of specimens; records are retained on site for 2 years</td>
</tr>
<tr>
<td>Clinical laboratory specimens</td>
<td>Suggested retention times:&lt;br&gt;48 hours—serum/CSF/body fluids (except urine)&lt;br&gt;24 hours—urine&lt;br&gt;7 days—peripheral blood smears/body fluid smears&lt;br&gt;7 days—microbiology permanently stained slides</td>
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Appendix B: Laboratory Developed Tests (AXB)

Laboratory Developed Tests
The US Food and Drug Administration (FDA) defines Laboratory Developed Tests (LDTs) as “a class of in vitro diagnostics that are manufactured, including being developed and validated, and offered, within a single laboratory.”

Historically, the components of LDTs were individually regulated by the FDA as Analyte Specific Reagents (ASRs) or other specific or general reagents. Today, many LDTs use complex elements and sophisticated technologies that may not be FDA-regulated. Because the FDA does not actively regulate them, LDTs that have not been properly validated for their intended use can result in missed diagnoses, wrong diagnoses, and failure to receive appropriate treatment for patients.

Laboratories performing LDTs are currently regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) by both proficiency and quality control testing requirements.

For laboratories performing LDTs, follow the standards listed in the Molecular Biology column of the Standards Applicability Grid (SAG), in addition to the following:

- DC.02.01.05
- DC.02.01.07
- EC.02.04.05
- HR.01.02.03, EP 4
- QSA.02.04.01
- QSA.02.10.01, EP 6
- QSA.02.10.01, EP 7
- QSA.02.10.03
- QSA.04.01.01
- QSA.04.02.01
- QSA.04.03.01
- QSA.04.04.01
Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing

- QSA.04.05.01
- QSA.04.06.01
- QSA.09.01.01
- QSA.09.02.01
- QSA.09.03.01
- QSA.09.03.03
- QSA.09.03.05
- QSA.09.04.01
- QSA.09.05.01
- QSA.09.06.01
- QSA.09.07.01
- QSA.09.07.03
- QSA.17.01.01
- QSA.17.01.03
- QSA.17.02.01
- QSA.21.01.01
- QSA.21.02.01
- QSA.21.03.01
- QSA.21.04.01
Appendix C: Individualized Quality Control Plan–Eligible Requirements (AXC)

On January 1, 2016, The US Centers for Medicare & Medicaid Services (CMS) implemented a new voluntary quality control (QC) option for clinical laboratories, the Individualized Quality Control Plan (IQCP). IQCP is applicable to all specialties and subspecialties except pathology and allows laboratories to customize QC policies and procedures based on a risk assessment of their health care setting.

This following table lists the general and specialty/subspecialty quality control requirements that are eligible for the IQCP approach. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP–eligible Joint Commission accreditation requirements.

<table>
<thead>
<tr>
<th>Quality System Assessment for Nonwaived Testing (QSA)</th>
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<tbody>
<tr>
<td>QSA.02.04.01, EPs 1-8</td>
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<td>QSA.02.06.01, EPs 1-4</td>
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<tr>
<td>QSA.02.07.01, EP 1</td>
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<tr>
<td>QSA.02.09.01, EP 2</td>
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<tr>
<td>QSA.02.10.01, EPs 1-10, 12</td>
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<td>QSA.02.10.03, EPs 3, 4</td>
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<tr>
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<td>QSA.04.01.01, EPs 1-7</td>
</tr>
<tr>
<td>QSA.04.02.01, EPs 1-4</td>
</tr>
<tr>
<td>QSA.04.03.01, EPs 1, 2, 4, 5</td>
</tr>
</tbody>
</table>

| QSA.04.04.01, EPs 1-4                                 |
| QSA.05.06.01, EP 2                                    |
| QSA.06.02.01, EPs 1-3                                 |
| QSA.06.04.01, EP 2                                    |
| QSA.06.04.03, EP 2                                    |
| QSA.06.04.05, EP 2                                    |
| QSA.09.03.03, EP 1                                    |
| QSA.10.04.01, EP 1                                    |
| QSA.11.01.01, EPs 4, 5                                |
| QSA.11.02.01, EPs 2-9                                 |
| QSA.12.01.01, EPs 7, 13, 14                           |

| QSA.04.04.01, EPs 1-4                                 |
| QSA.05.06.01, EP 2                                    |
| QSA.06.02.01, EPs 1-3                                 |
| QSA.06.04.01, EP 2                                    |
| QSA.06.04.03, EP 2                                    |
| QSA.06.04.05, EP 2                                    |
| QSA.09.03.03, EP 1                                    |
| QSA.10.04.01, EP 1                                    |
| QSA.11.01.01, EPs 4, 5                                |
| QSA.11.02.01, EPs 2-9                                 |
| QSA.12.01.01, EPs 7, 13, 14                           |

| QSA.12.02.01, EPs 5, 6                                |
| QSA.14.01.01, EP 1                                    |
| QSA.14.02.01, EP 2                                    |
| QSA.15.01.01, EP 3                                    |
| QSA.15.04.01, EP 4                                    |
| QSA.17.01.01, EPs 4, 5                               |
| QSA.17.02.01, EPs 1, 2                               |
| QSA.21.02.01, EPs 1-11                               |
| QSA.21.04.01, EPs 1-3                                |
Glossary (GL)

**accreditation**  Determination by The Joint Commission that an eligible organization complies with applicable Joint Commission accreditation requirements.

**accreditation contract**  The primary document that establishes the terms of the relationship between the organization and The Joint Commission.

**accreditation decisions**  Categories of accreditation that an organization can achieve based on a Joint Commission survey. These decision categories are as follows:

- **Limited, Temporary Accreditation**  The organization demonstrates compliance with selected standards in surveys conducted under the Early Survey Policy.
- **Accredited**  The organization is in compliance with all applicable standards at the time of the on-site survey or has successfully addressed all Requirements for Improvement (RFIs) in an Evidence of Standards Compliance (ESC) within 60 days following the posting of the Accreditation Survey Findings Report and does not meet any other rules for other accreditation decisions.
- **Accreditation with Follow-up Survey**  The organization is in compliance with all standards, as determined by an acceptable ESC submission. A follow-up survey is required within 6 months to assess sustained compliance.

- **Preliminary Denial of Accreditation**  There is justification to deny accreditation to the organization as evidenced by
  - An Immediate Threat to Health or Safety to patients or the public, and/or
  - Submission of falsified documents or misrepresented information, and/or
  - Lack of a required license or similar issue at the time of survey, and/or
  - Significant noncompliance with Joint Commission standards The decision is subject to review and appeal by the organization prior to the determination to deny accreditation.

- **Denial of Accreditation**  The organization has been denied accreditation. All review and appeal opportunities have been exhausted.

**accreditation manual**  A Joint Commission publication consisting of policies, procedures, and accreditation requirements relating to ambulatory care, behavioral health care, critical access hospital, home care, hospital, nursing care center, office-based surgery, and clinical laboratory and point-of-care testing. Organizations should use the manual that contains the set of accreditation requirements that is most appropriate to the primary focus or mission of the organization.
accreditation process  A continuous process whereby organizations are required to demonstrate to The Joint Commission that they are providing safe, high-quality care, as determined by compliance with Joint Commission standards, National Patient Safety Goals, and performance measurement requirements (as applicable). Key components of this process are an on-site evaluation of the organization by a Joint Commission surveyor(s) and, where applicable, quarterly submission of performance measurement data to The Joint Commission.

Accreditation Quality Report  See Quality Report.

accreditation survey  An on-site evaluation of an organization to assess its level of compliance with applicable Joint Commission accreditation requirements and to make determinations regarding its accreditation status. The survey includes evaluation of documentation of compliance provided by organization staff; verbal information concerning the implementation of standards or examples of their implementation that enable a determination of compliance to be made; on-site observations by the surveyor(s); and an opportunity for education and consultation regarding standards compliance and performance improvement.

accreditation survey findings  Findings from an on-site evaluation conducted by Joint Commission surveyors that result in an organization’s accreditation decision.

adverse event  A patient safety event that resulted in harm to a patient.

ambulatory health care  Health services provided to individuals who are not confined to institutional beds as inpatients during the time services are rendered. Ambulatory care services are provided in many settings ranging from freestanding ambulatory surgery facilities, to primary care settings, to diagnostic radiology; outpatient behavioral health services are not included.

anatomic pathology  Services related to surgical pathology, autopsy, and cytology.

annually  One year from the date of the last event, plus or minus 30 days. Synonymous with every 12 months, once a year, or every year.

appeal process  The process afforded to an organization that receives a Preliminary Denial of Accreditation decision, which includes the organization’s right to make a presentation to the Review Hearing Panel before accreditation is denied.

applicant organization  An organization that is seeking either accreditation for the first time or re-accreditation.

application for accreditation  See E-App.

assessment  An objective evaluation or appraisal of an individual’s health status, including acute and chronic conditions. The assessment gathers information through collection of data, observation, and physical examination.
**behavioral health care** A broad array of care, treatment, or services for individuals with mental health issues, foster care needs, addictive behaviors, chemical dependency issues, or intellectual/developmental disabilities. Care, treatment, or services can be provided in a wide variety of settings, such as inpatient/crisis stabilization, residential, day program, outpatient, and community-based settings.

**behaviors that undermine a culture of safety** Conduct by staff working in the organization that intimidates others to the extent that quality and safety could be compromised. These behaviors, as determined by the organization, may be verbal or nonverbal, may involve the use of rude language, may be threatening, or may involve physical contact.

**blind specimen** A sample with known value tested by personnel who do not know the expected result.

**blood component** A fraction of separated whole blood (for example, red blood cells, plasma, platelets, granulocytes).

**blood transfusion services** Services related to transfusing and infusing individuals with blood, blood components, or blood derivatives.

**calibration verification** The process used to verify a laboratory’s reportable range of individual results, which includes calibration materials with at least a minimal value, a midpoint value, and a maximum value. Calibration is verified based on manufacturers’ recommendations or instrument history, and whenever a major change in the reagents or equipment or instrument could affect the calibration. Federal regulations require that calibration verification is performed at least once every six months. See also reportable range.

**certification** For purposes of Joint Commission certification, determination by The Joint Commission that an eligible program or service complies with applicable Joint Commission certification requirements.

**Clinical and Laboratory Standards Institute (CLSI)** A global, nonprofit, standards-developing organization for clinical and laboratory services that promotes the development and use of voluntary consensus standards and guidelines within the health care community.

**clinical laboratory** See laboratory.

**Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)** Federal legislation that created uniform federal standards for regulating laboratory testing. CLIA ’88 unified the disparate federal and state standards regulating clinical laboratories and extended government oversight to all testing facilities, including physician offices.

**clinical leader** An individual with essential clinical knowledge who sets expectations, develops plans, and implements procedures to assess and improve the quality of the organization’s clinical and support functions and processes.
clinical practice guidelines  Tools that describe a specific procedure or processes found, through clinical trials or consensus opinion of experts, to be the most effective in evaluating and/or treating a mother and/or newborn, patient, resident, or individual served who has a specific symptom, condition, or diagnosis. Synonyms include practice parameter, protocol, clinical practice recommendation, preferred practice pattern, and guideline.

clinical staff  Individuals such as employees, licensed independent practitioners, contractors, volunteers, or temporary agency personnel who provide or have provided clinical services to the organization’s patients, residents, or individuals served. See also staff.

close call  A patient safety event that did not reach the patient; also called near miss or good catch.

complex organization  An organization accredited by The Joint Commission under more than one accreditation manual.

comprehensive systematic analysis  A process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis is one type of comprehensive systematic analysis.

confidentiality  Protection of data or information from being made available or disclosed to any unauthorized person(s) or process(es).

consultation  1. Provision of professional advice or services. 2. A review of an individual’s problem by a second practitioner and the rendering of an opinion and advice to the referring practitioner. In most instances, the review involves the independent examination of the individual by the consultant. 3. For purposes of Joint Commission accreditation, advice that is given to staff members of surveyed organizations relating to compliance with standards and requirements that are the subject of the survey.

continuity  The degree to which the care of individuals is coordinated among health care professionals, among organizations, and over time.

contract  A formal agreement for care, treatment, or services with an organization, agency, or individual that specifies the services, personnel, products, or space provided by, to, or on behalf of the organization and specifies the consideration to be expended in exchange.

contracted services  Services provided through a written agreement with another organization, agency, or person. The agreement specifies the services or personnel to be provided on behalf of the applicant organization and the fees to provide these services or personnel.

contractual agreement  An agreement with any organization, group, agency, or individual for services or personnel to be provided by, to, or on behalf of the organization. Such agreements are defined in
written form, such as in a contract, letter of agreement, or memorandum of understanding.

**Cooperative Accreditation Initiative** An initiative under which The Joint Commission relies on the process, findings, and decisions of other oversight accrediting organizations in circumstances where The Joint Commission would otherwise conduct potentially duplicative surveys of organizations seeking accreditation. Cooperative agreements are comparable to those of The Joint Commission. Entities that focus more on technical or clinical aspects of departments or services (for example, laboratory, rehabilitation units) are eligible for cooperative agreements because their accreditation requirements complement The Joint Commission’s by covering additional or more detailed aspects of care delivery.

**corrective maintenance** See maintenance.

**credentialing** The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care or services in or for a health care organization.

**credentials** Documented evidence of licensure, education, training, experience, or other qualifications.

**credentials verification organization (CVO)** Any organization that provides information on an individual’s professional credentials. An organization that bases a decision in part on information obtained from a CVO should have confidence in the completeness, accuracy, and timeliness of information. To achieve this level of confidence, the organization should evaluate the agency providing the information initially and then periodically as appropriate. The 10 principles that guide such an evaluation include the following:

1. The agency makes known to the user the data and information it can provide.
2. The agency provides documentation to the user describing how its data collection, information development, and verification process(es) are performed.
3. The user is given sufficient, clear information on database functions, including any limitations of information available from the agency (such as practitioners not included in the database), the time frame for agency responses to requests for information, and a summary overview of quality control processes related to data integrity, security, transmission accuracy, and technical specifications.
4. The user and agency agree on the format for transmitting credentials information about an individual from the CVO.
5. The user can easily discern what information transmitted by the CVO is from a primary source and what is not.
6. For information transmitted by the agency that can go out of date (for example, licensure, board certification), the CVO provides the date the information was last updated from the primary source.
7. The CVO certifies that the information transmitted to the user accurately represents the information obtained by it.
8. The user can discern whether the information transmitted by the CVO from a primary source is all the primary source information in the CVO’s possession pertinent to a given item or, if not, where additional information can be obtained.

9. The user can engage the CVO’s quality control processes when necessary to resolve concerns about transmission errors, inconsistencies, or other data issues that may be identified from time to time.

10. The user has a formal arrangement with the CVO for communicating changes in credentialing information.

**critical result** Test result that is abnormal to a degree that may indicate a life-threatening situation (also known as critical value).

**critical test** A test or examination that always requires rapid communication of results, whether those results are normal or abnormal.

**data integrity** The accuracy, consistency, and completeness of data that are protected in some way from corruption, misuse, or accidental exposure to unauthorized users.

**data source** A primary source used for data collection (for example, physical health and behavioral health information, personnel records, written agreements, safety incident log).

**dentist** An individual who has received either a doctor of dental surgery degree or a doctor of dental medicine degree and who is licensed to practice dentistry.

**disaster** A type of emergency that, due to its complexity, scope, or duration, threatens the organization’s capabilities and requires outside assistance to sustain care, safety, or security functions.

**discharge** The point at which an individual’s active involvement with an organization or program ends, and the organization or program no longer maintains active responsibility for the care of the individual. In ambulatory or office-based settings where episodes of care occur even though the organization continues to maintain active responsibility for the care of the individual, discharge is the point at which any encounter or episode of care (that is, an office or clinic visit for the purpose of diagnostic evaluation or testing, procedures, treatment, therapy, or management) ends.

**disruptive and inappropriate behavior** See behaviors that undermine a culture of safety.

**do-not-use abbreviations** See prohibited abbreviations.

**E-App** An electronic form used for collecting information pertaining to the applicant organization. Information collected on this form will be used to determine the accreditation requirements applicable to the organization, the types of surveyors needed, the length of survey, and the survey fee.
Early Survey Policy  A policy that permits an organization to achieve accreditation in a two-survey process. The first survey is limited in scope, and successful completion results in Preliminary Accreditation. Organizations receiving Preliminary Accreditation under this policy are not recognized by the Centers for Medicare & Medicaid Services (CMS) to meet the requirements for Medicare certification. The second survey addresses all accreditation requirements, and successful completion results in full accreditation and recognition by CMS if requesting deemed status. The CMS Regional Office makes the final determination regarding an organization’s Medicare participation and the effective date of participation.

element of performance (EP)  Specific action(s), process(es), or structure(s) that must be implemented to achieve the goal of a standard. The scoring of EP compliance determines an organization’s overall compliance with a standard.

emergency  An unexpected or sudden event that significantly disrupts the organization’s ability to provide care, treatment, or services or the environment of care itself or that results in a sudden, significantly changed or increased demand for the organization’s services. Emergencies can be either human-made or natural (such as an electrical system failure or a tornado), or a combination of both, and they exist on a continuum of severity.

Emergency Operations Plan (EOP)  An organization’s written document that describes the process it would implement for managing the consequences of emergencies, including natural and human-made disasters, that could disrupt the organization’s ability to provide care, treatment, and services.

entry  The process by which an individual comes into a setting, including screening and/or assessment by the organization or the practitioner to determine the capacity of the organization or practitioner to provide the care, treatment, or services required to meet the individual’s needs.

epidemic  A disease, such as influenza, that spreads rapidly, attacks many people in a geographic area, causes a high rate of morbidity or mortality, and then subsides. Epidemic applies especially to infectious diseases, as in an epidemic of cholera, but is also applied to any disease, injury, or other health-related event, such as an epidemic of teenage suicide.

every 36 months  Three years from the date of the last event, plus or minus 3 months.

every 6 months  Six months from the date of the last event, plus or minus 20 days.

Evidence of Standards Compliance (ESC) report  A report submitted by a surveyed organization, which details the action(s) that it took to bring itself into compliance with an accreditation requirement or clarifies why the organization believes that it was in compliance with the accreditation requirement for which it re-
ceived a Requirement for Improvement. An ESC report must address compliance at the element of performance level.

**family** A person or persons who play a significant role in an individual’s life. A family is a group of two or more persons united by blood or adoptive, marital, domestic partnership, or other legal ties. The family may also be a person or persons not legally related to the individual (such as a significant other, friend, or caregiver) whom the individual personally considers to be family. A family member may be the surrogate decision-maker if authorized to make care decisions for the individual should he or she lose decision-making capacity or choose to delegate decision making to another.

**Focused Standards Assessment (FSA)**
A requirement of the accreditation process whereby an organization reviews its compliance with a selected subset of applicable Joint Commission accreditation requirements (including the applicable National Patient Safety Goals, a selection of standards that address accreditation program-specific high-risk areas, and the organization’s Requirements for Improvement [RFIs] from its last biennial survey); completes and submits to The Joint Commission a Plan of Action (POA) for any accreditation requirement with which it is not in full compliance; and chooses whether to engage in a telephone discussion with a member of the Standards Interpretation Group staff to determine the acceptability of the POA or discuss any other area of concern. Alternatives for a Full FSA submission include FSA Option 1 (attestation that an FSA was completed, but not submitted to The Joint Commission), Option 2 (on-site survey with documented findings), and Option 3 (on-site survey without documented findings). The FSA encourages organizations to be in continuous compliance with Joint Commission accreditation requirements and helps them to identify and manage risk. The organization retains the option to complete self-assessment with all applicable accreditation standards in the FSA tool, available on the organization’s Joint Commission Connect™ extranet site. See also Intracycle Monitoring (ICM).

**full survey** An on-site survey that assesses an organization’s compliance with all applicable Joint Commission accreditation requirements. See also accreditation survey.

**functional exercise** An exercise that validates the coordination of the emergency response activities within the organization, including collaboration with planning and response partners. It is an operations-based exercise that is action-oriented and designed to validate plans, policies, agreements, and procedures; clarify roles and responsibilities; and identify resource gaps in an operational environment.

**governance** The individual(s), group, or agency that has ultimate authority and responsibility for establishing policy; maintaining quality of care, treatment, or services; and providing for organization man-
agement and planning. Governance may be a separate entity or it may fall within the medical advisory or executive committee. Other names for this group include the board, board of trustees, board of governors, board of commissioners, and partnership.

gross analysis/examination  Process by which pathology specimens are inspected macroscopically to obtain diagnostic information. The term "grossing" means inspecting specimens to gather diagnostically critical information such as size, shape, consistency, and presence of abnormalities, while the surgical specimen is being processed for further microscopic examination. Gross analysis/examination of surgical specimens is typically performed by a pathologist, or by a pathologist’s assistant working in surgical pathology.

hazardous materials and waste  Materials whose handling, use, and storage are guided or defined by local, state, or federal regulation, such as the Occupational Safety and Health Administration’s Regulations for Bloodborne Pathogens regarding the disposal of blood and blood-soaked items and the Nuclear Regulatory Commission’s regulations for the handling and disposal of radioactive waste. This also includes hazardous vapors (for example, glutaraldehyde, ethylene oxide, nitrous oxide) and hazardous energy sources (for example, ionizing or nonionizing radiation, lasers, microwave, ultrasound). Although The Joint Commission considers infectious waste as falling into this category of materials, federal regulations do not define infectious or medical waste as hazardous waste.

hazard vulnerability analysis (HVA)  A process for identifying potential emergencies and the direct and indirect effects these emergencies may have on the organization’s operations and the demand for its services.

health information  Any information, oral or recorded, in any form or medium, that is created by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse that relates to past, present, or future physical or mental health or condition; the provision of health care; or payment for the provision of health care to an individual.

history and physical  Information gathered about an individual using a holistic approach for the purpose of establishing a diagnosis and developing a plan for care, treatment, or services to address physical health issues. The history may include information about previous illnesses; previous medical or surgical interventions and response to treatment; family health history; and social, cultural, economic, and lifestyle issues that may affect the individual’s health and well-being. The physical involves the physical examination of the individual’s body by the following means: inspection, palpation, percussion, and auscultation. When used in concert with behavioral health care services, the history and physical may be used to rule out physical
causes for behavioral health conditions or to assess the impact of a medical diagnosis or treatment on a behavioral health condition.

**home care** The term that is generally used to refer to services provided in the home or in the community to recovering, disabled, or chronically ill persons and their families. These services may include some combination of professional health care services and personal care and supportive services. Professional health care services (also known as “skilled care”) may include physical and/or psychological assessment, nursing and medical care, medication teaching and administration, wound care, pain management, disease education and management, physical therapy, speech therapy, or occupational therapy. Home supportive care services (also known as “non-skilled care”) may include such things as light housekeeping, meal preparation, medication reminders, dressing, laundry, shopping, transportation, and companionship. In addition, home care can provide palliative care, respite care, hospice care, and other related services to those in need, including provision of medical equipment, medications, and supplies.

**Immediate Threat to Health or Safety** A threat that represents immediate risk and has or may potentially have serious adverse effects on the health or safety of the patient, resident, or individual served. These threats are identified on site by the surveyor.

**individualized quality control plan (IQCP)** A quality control option that allows laboratories to customize policies and procedures for nonwaived test systems based on a risk assessment of their health care settings.

**infection** The transmission of a pathogenic microorganism to a host, with subsequent invasion and multiplication, with or without resulting symptoms of disease.

**infection, epidemic** See epidemic.

**informed consent** Agreement or permission accompanied by full notice about the care, treatment, or service that is the subject of the consent. A patient must be apprised of the nature, risks, and alternatives of a medical procedure or treatment before the physician or other health care professional begins any such course. After receiving this information, the patient then either consents to or refuses such a procedure or treatment.

**initial survey** An accreditation survey of an organization that has not been accredited by The Joint Commission for at least four months or an accreditation survey of an organization undergoing its first Joint Commission survey.

**in-service** Organized educational activity designed to enhance the skills of clinical staff relevant to their disciplines and job responsibilities.

**instrument, waived testing** A waived testing device used for recording, measuring, or controlling. The levels of
operation vary from manual steps to full automation, and specialized knowledge and skill are required.

**instrument-based waived testing**  Tests with analysis steps that rely on the use of an instrument to produce a test result of a patient, resident, or individual served.

**integrity**  The property that data or information have not been altered or destroyed in an unauthorized manner.

**interdisciplinary**  An approach to care that involves two or more disciplines or professions (for example, social services, specialist consultation, nursing, medicine, therapies, spiritual support) collaborating to plan, treat, or provide care or services to a mother and/or newborn, patient, resident, or individual served and/or that person’s family.

**interval-based maintenance**  See maintenance.

**Intracycle Monitoring (ICM)**  A process to help accredited organizations at various touch points in the biennial accreditation cycle with their continuous compliance efforts. The process involves access to an ICM Profile available on the organization’s Joint Commission Connect™ extranet site. The ICM Profile identifies high-risk areas and related standards areas and displays them within a Focused Standards Assessment (FSA) tool, which allows organizations to conduct a self-assessment of standards to identify and manage risk in the organization. See also Focused Standards Assessment (FSA).

**knowledge-based information**  A collection of stored facts, models, and information that can be used for ongoing staff development, for designing and redesigning processes, and for solving problems. Knowledge-based information is found in the clinical, scientific, and management literature.

**laboratory**  A facility that is equipped to examine material derived from the human body to provide information for use in the diagnosis, prevention, or treatment of disease; also called clinical laboratory or medical laboratory.

**laboratory test order**  A request for laboratory testing sent to the laboratory in writing, electronically, or verbally with follow-up written authorization.

**leader**  An individual who sets expectations, develops plans, and implements procedures to assess and improve the quality of the organization’s governance, management, and clinical and support functions and processes. At a minimum, leaders include members of the governing body and medical staff, the chief executive officer and other senior managers, the nurse executive, clinical leaders, and staff members in leadership positions within the organization.

**licensed independent practitioner**  An individual permitted by law and by the organization to provide care, treatment, and services without direction or supervision. A licensed independent practitioner operates within the scope of his or her license, consistent with individually granted clinical
privileges. When standards reference the term licensed independent practitioner, this language is not to be construed to limit the authority of a licensed independent practitioner to delegate tasks to other qualified health care personnel (for example, physician assistants and advanced practice registered nurses) to the extent authorized by state law or a state’s regulatory mechanism or federal guidelines and organizational policy.

licensure  A legal right that is granted by a government agency in compliance with a statute governing an occupation (such as medicine, nursing, psychiatry, or clinical social work) or the operation of an activity in a health care occupancy (for example, skilled nursing facility, residential treatment center, hospital).

**Life Safety Code®** A set of standards for the construction and operation of buildings intended to provide a reasonable degree of safety during fires. These standards are prepared, published, and periodically revised by the National Fire Protection Association and adopted by The Joint Commission to evaluate health care organizations under its life safety management program.

**long term care**  See nursing care center.

**maintenance**  There are five types of maintenance — predictive, metered, corrective, interval-based, and reliability-centered:

1. Predictive maintenance - A type of maintenance strategy that provides the means to achieve reliability levels that exceed the performance of a piece of equipment or system. This strategy is designed to measure and track data significant to the piece of equipment or system. It confirms possible faults with the equipment, and specific repairs are completed before the equipment fails. Predictive analysis can be performed using advanced monitoring instruments and predictive software that collects data and performs an analysis. The data collected are analyzed, and corrective maintenance is performed when the equipment is performing outside the desired operating parameters.

2. Metered maintenance - Maintenance strategy based on the hours of run time or the number of times the equipment is used (for example, number of images processed).

3. Corrective maintenance - Maintenance strategy that restores a piece of equipment to operational status after equipment failure.

4. Interval-based maintenance - Maintenance done according to specific intervals (for example, calendar time, running hours). A number of periodic inspections or restoration tasks are completed, based on information/data obtained from the last equipment check.

5. Reliability-centered maintenance - A type of maintenance that begins with a failure mode and effects analysis to identify the critical equipment failure modes in a systematic and structured manner. The process then requires the examination of each critical failure mode
to determine the optimum maintenance policy to reduce the severity of each failure.

The chosen type of maintenance strategy must take into account cost, safety, and environmental and operational consequences. Some functions are not critical and may be allowed to “run to failure,” while other functions must be preserved at all cost. Reliability-centered maintenance emphasizes the use of predictive maintenance techniques in addition to traditional preventive measures (metered, corrective, and interval based).

**manufacturer**  Party responsible for the production, design, assembly, packaging and/or labeling of devices and test systems.

**medical device**  An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or another similar or related article, including a component part or accessory that is

1. recognized in the official National Formulary or the United States Pharmacopeia or any supplement to them;
2. intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in humans or other animals; or
3. intended to affect the structure or any function of the body of humans or other animals and that does not achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and that is not dependent on being metabolized for the achievement of any of its primary intended purposes.

**medical equipment**  Fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals.

**medical staff**  The group of all licensed independent practitioners and other practitioners privileged through the organized medical staff process that is subject to the medical staff bylaws. This group may include others, such as retired practitioners who no longer practice in the organization but who wish to continue their membership in the group, courtesy staff, scientific staff, and so forth. See also medical staff, organized.

**medical supplies**  Medical items, usually of a disposable nature, such as bandages, sterile drapes, and suture materials. These supplies differ from permanent or durable items, such as medical equipment and devices.

**metered maintenance**  See maintenance.

**mitigation, emergency**  Those activities an organization undertakes in attempting to reduce the severity and impact of a potential emergency. See also emergency.

**multidisciplinary team**  A group of staff members composed of representatives from a range of professions, disciplines, or service areas.
nursing The health profession dealing with nursing care and services as (1) defined by the Code of Ethics for Nurses with Interpretive Statements, Nursing’s Social Policy Statement, Nurses’ Bill of Rights, Scope and Standards of Nursing Practice of the American Nurses Association and specialty nursing organizations and (2) defined by relevant state, commonwealth, or territory nurse practice acts and other applicable laws and regulations.

nursing care center Individuals receiving care in this setting require rehabilitative, supportive, or palliative care. This care may include time-limited medically complex or rehabilitative care, dementia-specific memory care, long term nursing care, and other specialty care services. These services may be provided within a hospital, in an organization affiliated with a hospital, or in a freestanding organization. Synonyms used by the health care field for this setting include nursing home, long term care facility, and skilled nursing facility (SNF).

occupancy The purpose for which a building or portion thereof is used or intended to be used. Depending on the organization, occupancies may include ambulatory health care occupancy, business occupancy, health care occupancy, and residential occupancy.

business occupancy An occupancy used to provide outpatient care, treatment, day treatment, or other services that does not meet the criteria in the ambulatory health care occupancy definition (for example, three or fewer individuals at the same time who are either rendered incapable of self-preservation in an emergency or are undergoing general anesthesia).

office-based surgery practice A surgeon-owned or -operated organization (for example, a professional services corporation, private physician office, small group practice) that provides invasive procedures and administers local anesthesia, minimal sedation, conscious sedation, or general anesthesia that renders three or fewer patients incapable of self-preservation at any time, and is classified as a business occupancy.

organizational and functional integration The degree to which a component of an organization is overseen and managed by the applicant organization. Organizational integration exists when the applicant organization’s governing body, either directly or ultimately, controls budgetary and resource allocation decisions for the component or, where separate corporate entities are involved, there is greater than 50% common governing board membership on the board of the applicant organization and the board of the component. Functional integration exists when the entity meets at least three of the following eight criteria:

1. The applicant organization and the component use the same process for determining membership of licensed independent practitioners in practitioner panels or medical or professional staff and/or use the same process for cre-
dentialing and assigning of privileges or clinical responsibilities to licensed independent practitioners, and/or share a common organized medical or professional staff between the applicant organization and the component.

2. The applicant organization’s human resources function hires and assigns staff at the component and has the authority to terminate staff at the component, to transfer or rotate staff between the applicant organization and the component, and to conduct performance appraisals of the staff who work in the component.

3. The applicant organization’s policies and procedures are applicable to the component with few or no exceptions.

4. The applicant organization manages all operations of the component (that is, the component has little or no management authority or autonomy independent of the applicant organization).

5. The component’s clinical records are integrated into the applicant organization’s clinical record system.

6. The applicant organization applies its performance improvement program to the component and has authority to implement actions intended to improve performance at the component.

7. The applicant organization bills for services provided by the component under the name of the applicant organization.

8. The applicant organization and/or the component portrays to the public that the component is part of the organization through the use of common names or logos; references on letterheads, bro-

orientation  A process used to provide initial training and information while assessing the competence of clinical staff relative to job responsibilities and the organization’s mission and goals.

ownership  The entity that has ultimate control of resources and operation of the organization applying for accreditation.

pathology and clinical laboratory services  The services that provide information on diagnosis, prevention, or treatment of disease or the assessment of health, through the examination of the structural and functional changes in tissues and organs of the body that cause or are caused by disease. It also includes the biological, microbiological, serological, chemical, immunohematological, hematological, or other examination of materials derived from the human body.

patient  An individual who receives care, treatment, or services. Synonyms used by various health care fields include resident, patient and family unit, individual served, consumer, health care consumer, customer, or beneficiary.

patient identifiers  Information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended. Acceptable identifiers may be the individ-
ual's name, an assigned identification number, telephone number, or other person-specific identifier.

**patient safety event** An event, incident, or condition that could have resulted or did result in harm to a patient. See also adverse event, close call, sentinel event.

**performance improvement** The systematic process of detecting and analyzing performance problems, designing and developing interventions to address the problems, implementing the interventions, evaluating the results, and sustaining improvement.

**pharmacy services** Pharmaceutical care and services involving the preparation and dispensing of medications and medication-related devices and supplies by a licensed pharmacy, with or without the provision of clinical or consultant pharmacist services.

**physician** A doctor of medicine or doctor of osteopathy who, by virtue of education, training, and demonstrated competence, is granted clinical privileges by the organization to perform a specific diagnostic or therapeutic procedure(s) and who is fully licensed to practice medicine.

**Plan for Improvement (PFI)** For purposes of Joint Commission accreditation, an organization’s written statement that details the procedures to be taken and time frames to correct existing Life Safety Code® deficiencies. See also Life Safety Code, Statement of Conditions™ (SOC).

**Plan of Action (POA)** A plan detailing the action(s) that an organization will take in order to come into compliance with a Joint Commission accreditation requirement. A POA must be completed for each element of performance associated with a non-compliant accreditation requirement.

**point-of-care testing** Analytical testing performed at sites outside the traditional laboratory environment, usually at or near where care is delivered to individuals. Testing may be categorized as waived, moderate, or high complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). Testing may range from simple waived procedures, such as fecal occult blood, to more sophisticated chemical analyzers. Guided by CLIA requirements this testing may be under the control of the main laboratory, another specialized laboratory (for example, for arterial blood gas), or the nursing service (for example, for glucose meters). Point-of-care testing may also be known as alternative site testing, decentralized laboratory testing, or distributed site testing.

**practice guidelines** See clinical practice guidelines.

**practitioner** Any individual who is licensed and qualified to practice a health care profession (for example, physician, nurse, social worker, clinical psychologist, psychiatrist, respiratory therapist) and is engaged in the provision of care, treatment, or services. See also licensed independent practitioner.
**Glossary**

**predictive maintenance**  
See maintenance.

**preparedness, emergency**  
Activities an organization undertakes to build capacity and identify resources that may be used if an emergency occurs. See also emergency.

**primary source**  
The original source or an approved agent of that source of a specific credential that can verify the accuracy of a qualification reported by an individual practitioner. Examples include medical schools, nursing schools, graduate education, state medical boards, federal and state licensing boards, universities, colleges, and community colleges.

**privacy (of information)**  
The right of an individual to limit the disclosure of personal information.

**process measure**  
Data focusing on a method that leads to a certain outcome.

**proficiency testing**  
A peer comparison program used by laboratories to assess reliability of tests performed. Samples whose precise content is unknown are periodically provided to laboratories for testing, and the results are compared with those of other laboratories that perform the same tests.

**prohibited abbreviations**  
A list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization. For accreditation purposes, the prohibited list applies, at a minimum, to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on preprinted forms.

**protected health information**  
Health information that contains information such that an individual person can be identified as the subject of that information.

**Public Information Policy**  
A Joint Commission policy which specifies the information that The Joint Commission may release about accredited organizations. By submitting a signed accreditation contract, the organization is acknowledging that The Joint Commission may make available to the public the accreditation-related information in accordance with this policy.

**qualifications**  
Knowledge, education, training, experience, competency, licensure, registration, or certification related to specific responsibilities.

**quality assessment**  
Document that outlines continuous assessment of a quality control plan’s effectiveness.

**quality control**  
A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. The organization monitors processes and solves performance problems to achieve this purpose.

**quality control plan**  
Document that describes the practices, resources, and procedures for controlling the quality of a particular test process.
quality improvement  Continuous study and adjustment of an organization’s operations and processes to better meet staff and customer needs. Also known as continuous quality improvement, continuous improvement, organizationwide improvement, and total quality management.

quality of care, treatment, or services  The degree to which care, treatment, or services for individuals and populations increases the likelihood of desired health or behavioral health outcomes. Considerations include the appropriateness, efficacy, efficiency, timeliness, accessibility, and continuity of care; the safety of the care environment; and the individual's personal values, practices, and beliefs.

Quality Report  A publicly available report that includes relevant and useful information about the provision of safe quality care provided in individual Joint Commission–accredited and –certified organizations. Quality Reports are created at the organization level and contain information regarding an organization’s accreditation or certification status. These reports provide detailed information about an organization’s performance and how it compares to that of similar organizations; the organization’s accreditation and/or certification decision and the effective dates of the accreditation/certification award; the last full survey/review date and last on-site survey/review date; programs accredited and/or services certified by The Joint Commission, and programs or services accredited by other accrediting bodies; compliance with The Joint Commission’s National Patient Safety Goals; special quality awards, and for hospitals, performance on National Quality Improvement Goals. If an organization has achieved both Joint Commission certification and accreditation, its Quality Report will contain both certification and accreditation information; the organizations will also have a separate Certification Quality Report.

quantitative result  A test result that is measured as a discrete number.

quarterly  Every three months, plus or minus 10 days.

ratio  Relationship between two counted sets of data (for example, number of staff placed to number of days may be expressed as 200:28 if the number of staff equals 200 and the number of days equals 28).

rationale for a standard  A short paragraph that explains the justification for a standard; that is, why the standard is important or how it contributes to quality and/or safety. A rationale is not scored, and not every standard has a rationale.

read-back  A method used to ensure understanding of information being communicated, often used between members of a care, treatment, or service team. The process involves the receiver of a verbal or telephone order writing down the complete order or test result or entering it into a computer and then reading it back and receiving confirmation from the person who gave the order or test result.
record 1. An account compiled by physicians and other health care professionals of a variety of health information, such as assessment findings, treatment details, and progress notes. 2. Data obtained from the records or documentation maintained on a patient or resident in any health care setting (for example, hospital, home care, nursing care center, practitioner office). The record includes automated and paper medical record systems.

recovery, emergency The final phase of emergency management, related to strategies, actions, and individual responsibilities necessary to restore the organization’s services after an emergency. See also emergency.

reliability 1. The ability of an item to perform a required function under stated conditions. 2. In performance measurement, consistency in results of a measure, including the tendency of the measure to produce the same results twice when it measures some entity or attribute believed not to have changed in the interval between measurements. 3. Statistically, the degree to which scores are free from random error.

reliability-centered maintenance See maintenance.

reportable range The range of test values over which the relationship between the instrument, kit, or system’s measurement response is shown to be valid.

Requirement for Improvement (RFI) A recommendation that is required to be addressed in an organization’s Evidence of Standards Compliance in order for the organization to retain its accreditation. Failure to adequately address an RFI after two opportunities may result in a recommendation to place the organization in Accreditation with Follow-up Survey.

response, emergency Actions taken and procedures implemented by the organization when an emergency occurs. See also emergency.

restraint Any method (chemical or physical) of restricting an individual’s freedom of movement, including seclusion, physical activity, or normal access to his or her body that (1) is not a usual and customary part of a medical diagnostic or treatment procedure to which the individual or his or her legal representative has consented, (2) is not indicated to treat the individual’s medical condition or symptoms, or (3) does not promote the individual’s independent functioning.

Review Hearing Panel A panel of three individuals, including one member of The Joint Commission’s Board of Commissioners, which evaluates the facts of an organization appealing a Preliminary Denial of Accreditation.

risk assessment, proactive An assessment that examines a process in detail including sequencing of events, actual and potential risks, and failure or points of vulnerability and that prioritizes, through a logical process, areas for improvement.
based on the actual or potential impact (that is, criticality) of care, treatment, or services provided.

**root cause analysis (RCA)** See comprehensive systematic analysis.

**SAFER matrix** The Survey Analysis for Evaluating Risk™ (SAFER™) matrix gives a visual representation of the risk level of each Requirement for Improvement (RFI). Each observation reported by a surveyor is plotted on the SAFER matrix according to the risk level of the finding. The risk level is determined according to two factors: (1) the likelihood of the finding to cause harm to patients, staff, and/or visitors, and (2) the scope at which the finding was observed.

**safety** The degree to which the risk of an intervention (for example, use of a drug, or a procedure) and risk in the care environment are reduced for a patient and other persons, including health care practitioners. Safety risks may arise from the performance of tasks, from the structure of the physical environment, or from situations beyond the organization’s control (such as weather).

**safety management** Activities selected and implemented by the organization to assess and control the impact of environmental risk, and to improve general environmental safety.

**sampling** Selecting a subset from a larger group of units or observations that provides information that may be used to decide about the larger quantity.

**scope of services** The activities performed by governance, managerial, clinical, or support staff.

**security** Protection of people and property against harm or loss (for example, workplace violence, theft, access to medications). Security incidents may be caused by persons from outside or inside the organization.

**security, information** Administrative, physical, and technical safeguards to prevent unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

**semi-quantitative result** Results of tests that are more precise than qualitative tests (negative/positive results) but less precise than quantitative tests (numerical value), usually scored on a graded scale (for example, 1+, 2+, 3+).

**sentinel event** A patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm. Sentinel events are a subcategory of adverse events.

**staff** As appropriate to their roles and responsibilities, all people who provide care, treatment, or services in the organization, including those receiving pay (for example, permanent, temporary, part-time personnel, as well as contract employees), volunteers and health profession students. The definition of staff does not include
licensed independent practitioners who are not paid staff or who are not contract employees.

**standard** A principle of patient safety and quality of care that a well-run organization meets. A standard defines the performance expectations, structures, or processes that must be substantially in place in an organization to enhance the quality of care, treatment, or services.

**Statement of Conditions™ (SOC)** A proactive document that helps an organization do a critical self-assessment of its current level of compliance and describe how to resolve any *Life Safety Code*® deficiencies. The SOC was created to be a “living, ongoing” management tool that should be used in a management process that continually identifies, assesses, and resolves *Life Safety Code* deficiencies.

**sterilization** The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

**stored emergency power supply systems (SEPSS)** Systems that automatically supply illumination or power to critical areas and equipment essential for safety to human life. Included are systems that supply emergency power for such functions as illumination for safe exiting, ventilation where it is essential to maintain life, fire detection and alarm systems, public safety communications systems, and processes where the current interruption would produce serious life safety or health hazards to patients, residents, individuals served, the public, or staff. Note: Other non-SEPSS battery back-up emergency power systems that an organization has determined to be critical for operations during a power failure (for example, laboratory equipment, electronic medical records) should be properly tested and maintained in accordance with manufacturer recommendations.

**surveillance** Systematic method of collecting, consolidating, and analyzing data concerning the frequency or pattern of, and causes or factors associated with, a given disease, injury, or other health condition. Data analysis is followed by the dissemination of that information to those who can improve outcomes. Examples of surveillance data can include ventilator associated pneumonia, antibiotic prophylaxis, hemodialysis catheter infections, implant infections, surgical site infections, hand hygiene, drug resistant organisms (MRSA, VRE), equipment sterile processing, vaccinations, urinary tract infections, and health care worker immunization.

**survey** A key component in the accreditation process whereby a surveyor(s) conducts an on-site evaluation of an organization’s compliance with Joint Commission accreditation requirements.

**surveyor** For purposes of Joint Commission accreditation, a health care professional who meets The Joint Commission’s surveyor selection criteria, evaluates compliance with accreditation requirements, and provides education regarding compliance with accreditation requirements to surveyed organizations or systems. The
type of surveyor(s) assigned is determined by the accreditation program and its services. A surveyor may be, but is not limited to, a licensed physician, surgeon, pediatrician, dentist, nurse, physician assistant, pharmacist, medical technologist, respiratory therapist, administrator, social worker, psychologist, or behavioral health care professional.

tabletop exercise An exercise that involves key personnel discussing simulated scenarios and is used to assess plans, policies, and procedures. It is a discussion-based exercise that familiarizes participants with current plans, policies, agreements, and procedures, or may also be used to develop new plans, policies, agreements, and procedures.

test system Instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

The Joint Commission An independent, not-for-profit organization dedicated to improving the safety and quality of health care through standards development, public policy initiatives, accreditation, and certification. The Joint Commission accredits and certifies more than 20,000 health care organizations and programs in the United States.

tissue Any group of cells that perform specific functions.

tracer methodology A process surveyors use during the on-site survey to analyze an organization’s systems or processes for delivering safe, high-quality care by following an individual patient or resident through the organization’s care process in the sequence experienced by each individual. Depending on the setting, this process may require surveyors to visit multiple care programs and services within an organization or within a single program or service to “trace” the care rendered.

transmission-based precautions Infection prevention and control measures to protect against exposure to a suspected or identified pathogen. These precautions are specific and based on the way the pathogen is transmitted. Categories include contact, droplet, airborne, and a combination of these.

uniform data set An agreed-on and accepted set of terms and definitions constituting a core of data; a collection of related data items.

utility systems Building systems that provide support to the environment of care, including electrical distribution and emergency power; vertical and horizontal transport; heating, ventilating, and air conditioning (HVAC); plumbing, boiler, and steam; piped gases; vacuum systems; and communication systems, including data exchange systems.

validity Within a data and information management context, demonstration that a measure set brings about the results intended.
**variance**  A measure of the difference in a set of observations; statistically, the square of the standard deviation.

**waived testing**  Tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) requirements for waived tests and are cleared by the Food and Drug Administration for home use. These tests employ methodologies that are so simple and accurate that the likelihood of erroneous results is negligible, or they pose no risk of harm to the patient, resident, or individual served if the test is performed incorrectly. See also Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88).

**weekly**  Once every seven days, plus or minus two days.
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