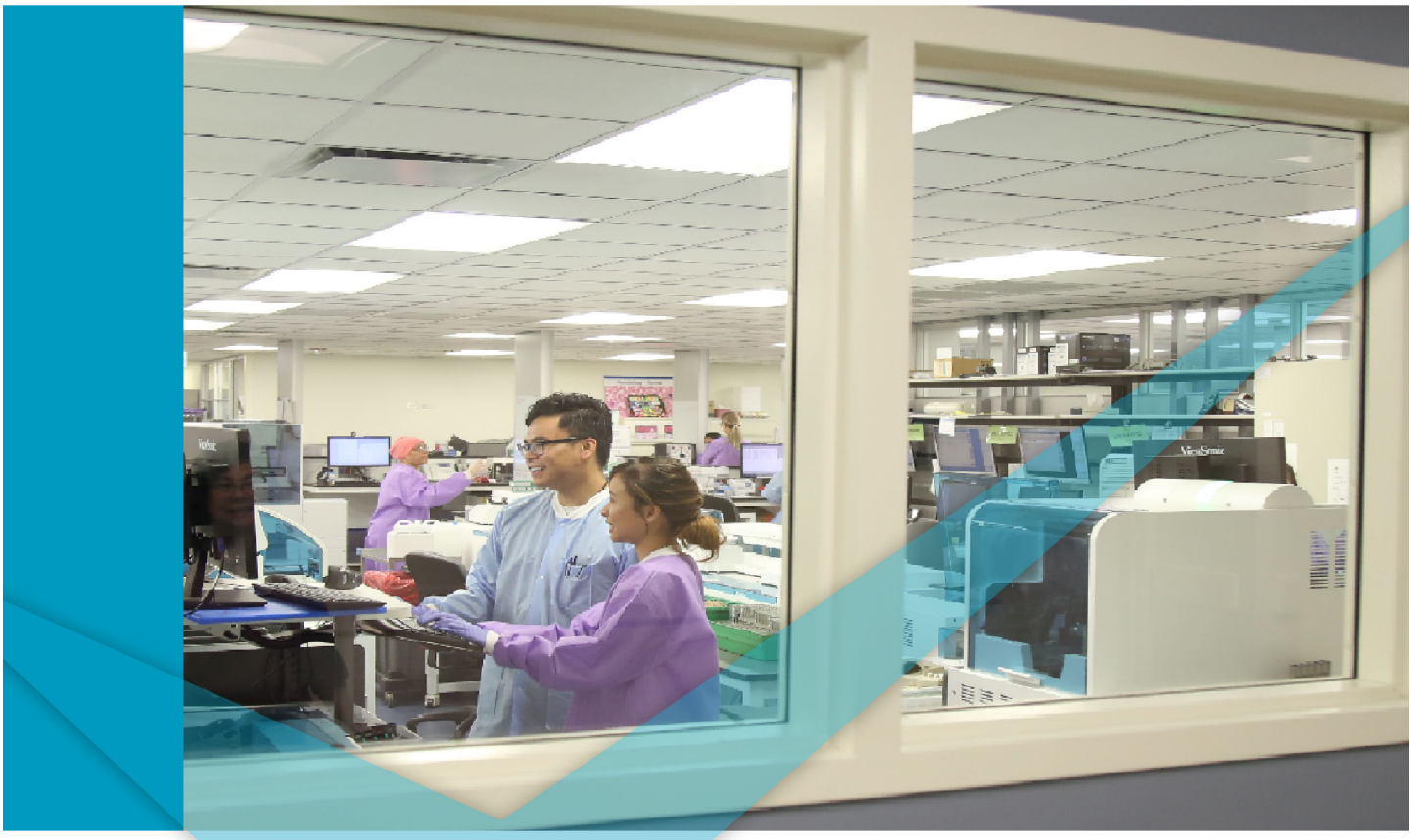
COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Guide to CAP Accreditation



ACCREDITATION PROGRAMS

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LABORATORY ACCREDITATION AND THE COLLEGE OF AMERICAN PATHOLOGISTS

About the CAP Laboratory Accreditation Program

We are experts in laboratory accreditation because that is our exclusive focus. Our programs help laboratories stay current with the ever-evolving changes of laboratory medicine and technology, as well as the regulatory landscape through the input of our pathologist members and laboratory professionals around the world. As a result, CAP Accreditation is globally recognized as the most rigorous choice to achieve and maintain regulatory compliance.

Our annually updated accreditation checklists provide a road map for running a high-quality laboratory while simplifying the accreditation process. The checklists are used by the laboratory to prepare for inspections and by the inspection team as a guide to assess the overall quality of the laboratory and compliance with CAP checklist requirements. CAP inspections are educational, not punitive. Our unique, reciprocal, peer inspection model benefits both the laboratories being inspected and the laboratories providing the inspection teams.

Only the CAP offers an engaging, dynamic, collaborative process that fosters an environment of continuous improvement to ensure the highest quality patient care.

What to expect by participating in the CAP Laboratory Accreditation Program?

A laboratory inspection with a CAP-provided team occurs every two years. In the years when an external inspection does not occur, the laboratory performs a self-inspection using materials provided by the CAP.

Prior to inspection, the laboratory is provided with customized checklists based on the laboratory's testing menu. The inspection team will use the same customized checklists during the inspection.

Following the completion of an inspection, the inspector will provide the summary of inspection findings to the laboratory staff. The laboratory has 30 days to submit responses to identified deficiencies to the CAP. After successfully meeting all the requirements, the laboratory is awarded a "CAP Laboratory Accreditation" certificate and becomes part of an exclusive group of over 8,000 laboratories worldwide that have met the highest standards of excellence.

TEN STEPS TO CAP LABORATORY ACCREDITATION

1 Request Application	▪ Fill out and submit the Request for Application* form at cap.org. *Note for **International laboratories**: you must be enrolled in CAP Proficiency Testing (PT)/External Quality Assurance (EQA) for a **minimum of six months** before requesting an application.
2 Review Welcome Kit	▪ Check your email to access the link to the online application (look for "CAP Accreditation Application Available" in the email subject line). ▪ Review additional information enclosed with the application link on how to get started with the accreditation process. ▪ Schedule an optional onboarding call with CAP staff who will guide you through the next steps in the accreditation process and answer questions.
3 Complete Application	▪ Complete the accreditation application within 3 months from the day it becomes available online. ▪ Review the due date on the homepage after you log in. ▪ Monitor email reminders that the CAP will send out as the application due date approaches. ▪ Work with the CAP staff on any follow-up questions during application review. ▪ Laboratories have the option to upload a preselected set of documents for review by the inspectors up to four months prior to the inspection.
4 Receive Customized Checklists	▪ Receive customized checklists by mail and begin inspection preparation and/or ▪ Download customized checklists online by logging into your account if you prefer electronic checklists.
5 Schedule Inspection Date	▪ Look for a letter in the mail (sent to the accreditation contact from your laboratory) announcing the inspection team leader's name and organization. ▪ Schedule** the inspection date with the inspection team leader (the team leader will contact the laboratory director to set the inspection date). ▪ Prepare for the initial inspection that will take place within 6 months after the submission of the online application. ▪ For inspections with advance document review, share the guest access link to your document management system by the designated date so that the inspection can proceed smoothly **Note: After the first inspection, future routine inspections are performed within the 90-day period preceding the laboratory's two-year anniversary date. The timing for advance notification of the inspection date from the team leader varies based on the accreditation program type and location of the laboratory. US laboratories accredited under the Laboratory Accreditation Program receive a two-week notification from the team leader for routine inspections. For international laboratories and specialty accreditation programs, subsequent routine inspections are announced.

	All inspections are performed within the 90-day period preceding the anniversary date.
6 Host Inspection Day	The laboratory should: ▪ expect the arrival of the inspection team, which will conduct the inspection with the same customized checklists that you received earlier. ▪ support the inspection team as needed or requested. ▪ receive a copy of the preliminary inspectors summary report from the inspection team leader (given to the laboratory director) during the summation conference. ▪ Receive email (sent to the laboratory director) with a link to the post inspection critique within 7 days following the inspection. ▪ Complete and return the critique with feedback about the inspection to cdm@cap.org
7 Respond to Deficiencies Within 30 Days	▪ Review the instructions for responding to deficiencies provided by the inspection team. ▪ Submit all responses online within 30 calendar days after the inspection date.
8 Support CAP Review of Responses	▪ Contact the CAP technical specialists with questions about responding to deficiencies. ▪ Promptly respond to requests from the technical specialist to provide additional documentation when needed to complete the review of deficiency responses. ▪ Anticipate an accreditation decision within 50 days of the inspection date.
9 Receive Certificate of Accreditation	▪ Look for the laboratory's CAP Certificate of Accreditation by mail, sent to the attention of the laboratory director. ▪ Mark your calendar with the anniversary date displayed on the certificate.
10 Perform Self-Inspection and Maintain Continuous Compliance	▪ Receive materials from the CAP and conduct a self-inspection around the laboratory's one-year anniversary date. Correct deficiencies identified during the self-inspection and retain records of these activities. ▪ Make changes in laboratory directorship, location, name, ownership, test menu, roles, and personnel by logging into e-LAB Solutions Suite at any time. ▪ Enroll in or discontinue PT/EQA products when the test menu changes, if needed, by contacting the CAP Customer Contact Center or visiting our online store. ▪ Note that the accreditation cycle repeats every two years, starting with completing the reapplication in Step 3, seven months prior to the two-year anniversary date.

THINGS TO KNOW FOR CAP LABORATORY ACCREDITATION

Eligibility

The laboratory must have a qualified laboratory director, successfully participate in the appropriate proficiency testing/external quality assurance and actively performing laboratory testing.

Director Qualifications

The CAP requires specific qualifications for the laboratory director, the person responsible for operation of the laboratory. Qualifications of the director may differ based on the type and complexity of the testing performed. A laboratory director must be a licensed physician (MD, DO) or doctoral scientist (PhD, DPH), with the necessary qualifications (experience, certification, and continuing education credit hours) to meet personnel requirements as determined by the CAP.

Laboratory Personnel Qualifications

CAP requires that all high complexity testing personnel have earned at least a minimum of an associate degree in a laboratory science or medical technology from an accredited institution or equivalent education. Personnel performing moderately complex testing must have earned at least a high school diploma or equivalent. Refer to the CAP Personnel Guidance Document for a detailed listing of the qualifications for all supervisory roles and testing personnel.

The laboratory must retain records that all testing personnel have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

Proficiency Testing (PT)/External Quality Assurance (EQA)

Proficiency Testing (PT)/External Quality Assurance (EQA) is an interlaboratory peer program that compares a laboratory's test results using unknown specimens to results from other laboratories using the same or similar methods. Laboratories subject to US regulations must enroll and participate in a CAP-accepted PT program for all required analytes (see the Master Activity Menu to determine which analytes require enrollment in PT).

For international laboratories, the laboratory must enroll in all available CAP PT/EQA a minimum of six months prior to requesting a CAP application.

This time frame enables the international laboratory to become familiar with the requirements necessary to obtain permits and any other documents needed to receive PT/EQA shipments.

Key Components

To meet CAP Laboratory Accreditation requirements, the laboratory must have the following key documents/processes:

- Quality Management System
- Chemical Hygiene Plan
- Document Control Process
- Competency Assessment Program
- Test Method Validation and Verification Records
- Laboratory Director Oversight Records

- Laboratory Information System (LIS) – if applicable

Additional Resources

The following products and documents are available from the CAP to assist laboratories in the process of preparing for accreditation *as part of the non-refundable accreditation application fee*:

- Focus on Compliance Webinars
- Online Inspector Training
- CAP Accreditation Checklists
- Laboratory Accreditation Manual
- Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox
- Standards for Laboratory Accreditation
- CAP Accreditation Resources Online Repository
- CAP Personnel Guidance Document

The following items are available for an additional fee:

- CAP Accreditation Readiness Assessment (CARA)
- Online Competency Assessment Program
- Quality Management Tools
- Quality Cross Check Programs
- Calibration Verification/Linearity Programs

Cost of Accreditation

Annual accreditation fees are based on the institution's laboratory sections, list of testing performed (activity menu), organization structure, and complexity.

To receive an estimate of annual accreditation fees, complete and submit the Accreditation Fee Estimate form online at cap.org.

International laboratories are required to pay for roundtrip, business-class airfare for intercontinental travel for inspector(s). The number of inspectors sent will be based on the volume and/or type of testing performed by the laboratory. The CAP will pay for all hotel accommodations, meals, ground transportation and in-country air travel. Inspections typically occur once every two years.

Please note that accreditation fees do not include the cost of proficiency testing/external quality assurance.

APPLICATION PROCESS

Overview

The application process involves two steps:

1) Request for application; and

2) Completion of the online application in Organization Profile by logging into e-LAB Solutions Suite on cap.org.

Request for Application

Download the Accreditation Request for Application form at cap.org.

- Complete the form
- Submit via email or mail (instructions provided on form)
- Include the one-time, nonrefundable application fee
  - Credit card
  - Wire transfer
  - Check

What's Next?

After the Request for Application is processed by the CAP, the laboratory will receive an email notification with instructions for accessing the online Organization Profile through the CAP's online resource (e-LAB Solutions Suite).

Online Application

Once all tasks are completed in the laboratory's Organization Profile, click on the "Application Complete" button.

For assistance, contact the Customer Contact Center at 800-323-4000 or for international customers at +001-847-832-7000 or email accreditationonline@cap.org.

The applications must be completed within three months of receipt by the laboratory.

DIRECTOR RESPONSIBILITIES

What are the Director's Responsibilities?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists. The director must have the qualifications and authority to fulfill these responsibilities effectively.

Key Components

An effective director ensures:

- The following components are defined, implemented, and monitored:
  - An effective quality management system.
  - An adequate number of appropriately trained and qualified personnel.
  - A safe laboratory environment.
- Availability of consultations for ordering appropriate tests and the interpretation of the medical significance of laboratory data.
- Anatomic pathology services are provided by a qualified anatomic pathologist.
- The ability to function effectively with applicable accrediting and regulatory agencies, the medical community, patients, and administrative officials.
- Educational programs, strategic planning, research, and development appropriate for the laboratory and institution.
- Qualified section directors for all sections of the laboratory if the laboratory director is not qualified to direct any of the individual sections.
- If delegating activities to others, documentation specifying which individuals are authorized to act on his/her behalf.
- A written policy or agreement defining involvement of the laboratory director, including activities performed on-site and through remote consultation.
- If the laboratory director is not routinely on-site, records of on-site visits with evidence of activities demonstrating the director responsibilities to occur:
  - At least every six months (with at least four months between the two on-site visits) for laboratories subject to US regulations.
  - At least once per year for laboratories not subject to US regulations.

Who Is Responsible?

The director of a CAP-accredited laboratory is responsible for ensuring ongoing compliance with the Standards for Laboratory Accreditation and implementing the requirements of the accreditation checklists.

Outcome of an Effective Director

Laboratory benefits include:

1. A culture committed to continuous improvement.

2. An involved director who serves as a mentor and promotes a culture of quality.
3. A safe environment.
4. Ongoing compliance with the CAP requirements.
5. A testing environment always prepared for an inspection.

LABORATORY DIRECTOR QUALIFICATIONS

Laboratories subject to US regulations	
High Complexity Testing	1. MD, DO, or DPM licensed to practice in the jurisdiction where the laboratory is located (if required), **and** have **one** of the following: - Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, or - Have at least two years of experience supervising high complexity testing **OR** 2. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and:** - Have **current** certification by a board approved by HHS*, **and** - Have at least two years of laboratory training or experience or both, and laboratory experience directing or supervising high complexity testing, **and**
Moderate Complexity Testing	1. Qualified as in (1) above **OR** 2. MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), **and** - At least one year of experience supervising non-waived laboratory testing, **or** - Have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist **OR** 3. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and:** - Have current certification by a board approved by HHS*, **and** - At least one year of experience directing or supervising non-waived testing
Provider Performed Microscopy Testing	1. MD or DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required)
Waived Testing	1. MD, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required) **OR** 2. Doctoral degree in a chemical, biological, or clinical laboratory science from an accredited institution

Laboratories not subject to US regulations	
All Testing Complexities	1. MD or DO licensed to practice in the jurisdiction where the laboratory is located (if required) **and** have **one** of the following: – Certification in anatomic or clinical pathology; or – At least one year of laboratory training during medical residency/fellowship; or – At least two years of experience supervising high complexity testing **OR** 2. Doctoral degree (PhD, DPH, or equivalent) in a chemical, biological, or clinical laboratory science **and** have **both** of the following: – At least two years of clinical laboratory training or experience **and** – Two years of laboratory experience directing or supervising high complexity testing

**A list of boards approved by CMS for doctoral scientists may be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html*

Detailed information on qualifications for laboratory directors subject to US regulations may be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

Training and experience must relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition.

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed to ensure that their training and qualifications are equivalent to CLIA requirements, with records of the review available on site. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required and qualifications are at least as stringent as CLIA. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.

A single individual may direct no more than five laboratories (not including laboratories that perform only waived testing) and may not direct more laboratories than permitted by national, federal, state (or provincial), or local law.

If more stringent state or local regulations are in place for laboratory director qualifications, including requirements for licensure, they must be followed.

Additional qualifications for laboratory directors are included for the following types of testing or services:

- *For the specialty of dermatopathology, the director may qualify as defined in the CLIA regulation 42CFR493.1449(f).*
- *For the subspecialty of **oral pathology,** the director must be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.*
- *Qualifications for **histocompatibility section directors/technical supervisors**, including continuing clinical laboratory education requirements, can be found in the Histocompatibility Checklist.*
- *For laboratories participating in the **Reproductive Laboratory Accreditation Program**, directors of laboratories performing andrology testing must meet the requirements described above for high complexity testing and have at least two years of experience in a laboratory performing andrology procedures. This experience must include quality management, quality control, inspection, accreditation, and licensing procedures, as well as andrology procedures. Requirements for embryology laboratory directors are found in the Reproductive Laboratory Medicine Checklist in RLM.10166.*
- *For laboratories participating in the **Forensic Drug Testing Accreditation Program**, specific requirements for laboratory director/scientific director are in the Forensic Drug Testing Checklist.*

DOCUMENT CONTROL SYSTEM

What is Document Control?

Document control is the management of all paper or electronic documents, including policies, procedures, and forms. A written document control system outlines how all documents are initiated or revised, approved, utilized, reviewed, retained, and discontinued.

Every document within the laboratory must be:

- Current – have up-to-date review and reflect current practices.
- Accurate – only authorized revisions are made to documents, substantial revisions are reviewed and approved before implementation, and revisions are reflected on all copies of documents.
- Available – readily accessible to all staff utilizing them.

Key Components

A laboratory's document control system must ensure:

- All copies of policies, procedures, and forms are current.
- Personnel have read the policies and procedures relevant to their job activities.
- Personnel are knowledgeable about the contents of procedure manuals (including changes) and demonstrate proficiency relevant to the scope of their testing activities.
- All policies and procedures have been authorized by the laboratory director before implementation.
- Policies and procedures are reviewed at least every two years by the laboratory director or designee.
- Discontinued policies and procedures are quarantined in a separate file for a minimum of two years from the date of discontinuation (five years for transfusion medicine).

Who is Responsible?

The laboratory director who meets CAP director qualifications is responsible for implementing and maintaining an effective document control program.

Outcome of an Effective System

The laboratory will benefit by:

- Ensuring on any given day practice matches policies and procedures.
- Promoting the use of only approved policies, procedures, and forms.
- Organizing procedures for ease of accessibility by testing personnel.
- Tracking the status of approvals and reviews to ensure they occur in a timely manner in accordance with CAP requirements.
- Maintaining ongoing compliance with CAP requirements.

CHEMICAL HYGIENE PLAN

What is a Chemical Hygiene Plan?

A Chemical Hygiene Plan (CHP) includes procedures to protect employees from the health hazards of chemicals and keep exposures below specified limits. All personnel involved in the laboratory must receive training on the CHP and understand how it applies to their role.

Key Components

An effective CHP includes:

- Defined laboratory director responsibilities and the designation of a chemical hygiene officer.
- Safety data sheets (SDS) for all hazardous chemicals used in the facility. The SDS must be accessible for review by all laboratory employees during every work shift.
- A training program on interpreting chemical labels and SDS, and the use of proper protection for chemical handling and disposal.
- Proper labeling on all chemical containers.
- Informing all laboratory employees of the right to know the hazards associated with their job.
- Evaluation of every chemical used in the laboratory for carcinogenic potential, reproductive toxicity, and acute toxicity.
- Annual review of the effectiveness of the CHP to include review of all incidents and occurrences of the past year.

Who is Responsible?

The laboratory director is responsible for the CHP.

Outcome of an Effective System

The laboratory will benefit by:

- Increased employee safety and awareness.
- Reduction in laboratory accidents and improved spill responses.
- Safe and efficient organization for chemical storage.
- Ongoing compliance with CAP requirements.

LABORATORY INFORMATION SYSTEMS (LIS)

What is a Laboratory Information System?

Laboratory information systems (LIS) provide a database serving the information needs of the laboratory by linking patient test results to the ordering clinician/client, and to the patient's medical record.

Overview

Multiple types of LIS are available, including:

- Systems with a local host database (computer hardware and software on site) where the laboratory is the only user.
- Systems with a host physically removed from the laboratory, where multiple user laboratories may share the same database.

The Laboratory Accreditation Program does not consider the following types of devices as an LIS:

- Small programmable technical computers or dedicated microprocessors that are an integral part of an analytic instrument.
- Purchased software services used for quality assurance and data analysis.
- Microcomputers used for word processing, spreadsheets, or other similar single-user functions.

Key Components

The laboratory must ensure the following:

- Computer facility and equipment with appropriate environmental controls and safety elements.
- Written LIS policies and procedures with instructions for daily operations appropriate to the level of use.
- Training for all users of the system relevant to the scope of their duties.
- Testing of the LIS for proper functioning at installation and when changes are made.
- System security policies and practices for user authentication, user authorization privileges, protection against unauthorized alterations, and network security.
- Error detection and timely communication of patient data to the ordering clinician/client.
- Validation of autoverification (if used) initially and when changes are made to the system that can affect the autoverification logic. Autoverification is a process where the LIS has defined parameters that allow results to flow from an interfaced instrument to the medical record without technical intervention or review. Defined system logic prevents the release of test results not meeting the defined parameters or criteria.
- Accurate transmission of data across instrument interfaces and interfaces with other computer systems (eg, middleware, hospital information systems, and other output devices).
- Data retrieval and preservation for the required regulatory retention period available, within a time frame consistent with patient care needs.

Who is Responsible?

The laboratory director is responsible for ensuring communication of laboratory data.

The director may delegate some LIS-related functions to others and is responsible for determining the qualifications of these individuals. It is the director's overall responsibility to ensure these functions are properly carried out.

Outcome of an Effective System

The laboratory benefits include:

- Accurate and timely transmission of patient data.
- Effective presentation of patient data.
- Retention and retrieval of patient data consistent with regulatory requirements.
- Improved efficiency and productivity in the laboratory.
- Ongoing compliance with CAP requirements.

TEST METHOD VALIDATION AND VERIFICATION

What is Test Method Validation and Test Method Verification?

Prior to clinical use of each test, the laboratory is required to establish or verify the test method performance specifications to ensure that the test is adequate to meet clients' needs.

Analytical **test method verification** is the process by which a laboratory determines that an **unmodified** FDA-cleared or approved test performs according to the specifications set forth by the manufacturer when used as directed. For laboratories not subject to US regulations, this also includes **unmodified** tests approved by an internationally recognized regulatory authority (eg, the European Union's Conformité Européenne (CE) Marking).

Analytical **test method validation** is the process used to confirm with objective evidence that a laboratory-developed test (LDT) or **modified** FDA-cleared or approved test delivers reliable results for the intended application. For laboratories not subject to US regulations, this also includes **modified** tests approved by an internationally recognized regulatory authority (eg, the European Union's Conformité Européenne (CE) Marking).

Overview

The test method validation or verification process must include:

- Written procedures describing the validation or verification process for new instruments and methods.
- Documentation of data collected in the testing environment where the method will be implemented.
- Data obtained from studies performed by the manufacturer and from published literature, as applicable.
- Written assessment of the validation or verification studies by the laboratory with approval by the laboratory director or designee meeting CAP director qualifications prior to initiation of patient testing.

Key Components

- The type of method validation/verification required is dependent on the type of testing as defined by the CAP.
- For waived testing, laboratories must follow manufacturer's instructions for introduction of the instrument or device and have records that the test has been approved for use.
- For **unmodified**, nonwaived FDA-cleared or approved tests (and tests approved by an internationally recognized regulatory authority for laboratories not subject to US regulations), the laboratory must verify the following test method performance specifications, as applicable:
  - Analytical accuracy – closeness of agreement between a test result and an accepted reference value.
  - Analytical precision – reproducibility of a test result.
  - Analytical interferences– ability of an analytic method to detect only

the analyte it was designed to measure.

- Reportable range – interval of test results for which the laboratory can establish or verify accuracy.
- Reference intervals – range of test values expected for a designated population.
- All other characteristics required for test performance.

- For laboratory-developed tests (LDTs) and **modified** FDA-cleared or approved tests, the laboratory must establish all test method performance specifications listed above, as well as the following, as applicable:
  - Analytical sensitivity – the lowest concentration or amount of the analyte or substance that can be measured with clinically meaningful reliability. Methods for determining the analytical sensitivity include lower limit of quantitation and limit of detection, although the limit of blank may be used if considered to be appropriate by the laboratory director.
  - Analytical specificity – ability of a test to correctly identify or quantify an entity in the presence of an interfering or cross-reactive substance that may be expected to be present.
  - Other performance characteristics required to ensure analytical test performance – examples include specimen and reagent stability, linearity, carryover, and cross-contamination.
  - Clinical performance characteristics – includes statements about a test's sensitivity and specificity and may include determining predictive values for a relevant disease or condition, as applicable, for LDTs.

Who is Responsible?

The laboratory director or designee who meets CAP director qualifications is responsible for ensuring each method performed is of sufficient scope and scientifically valid. The director or designee documents final approval of the validation or verification prior to the initiation of patient testing.

Outcome of an Effective System

The laboratory benefits include:

- Organized and clear evidence of test method validation and verification.
- Accurate patient test results when the new method is implemented.
- Ongoing compliance with CAP requirements.

COMPETENCY ASSESSMENT PROGRAM

What is Competency Assessment?

A competency assessment program appraises an individual's knowledge and mastery of skills needed to properly perform a specific job.

Key Components

Assessment of competency involves evaluation of the applicable elements of competency by a qualified individual for each test system at the required frequency.

Six Elements of Competency Assessment

- Direct observations of test performance.
- Monitoring of test result reporting.
- Review of quality control records, proficiency testing results, and preventive maintenance records.
- Direct observation of instrument maintenance and function checks.
- Assessment of test performance by external proficiency testing or internal blind testing samples.
- Evaluation of problem-solving skills.

System Components

A laboratory must have a process ensuring:

- Competency assessment is performed at the required frequency:
  - Nonwaived testing - at least semiannually during the first year an individual tests patient specimens and annually thereafter.
  - Waived testing - after an individual has performed assigned duties for one year, and at least annually thereafter.
- All test systems used for patient testing are defined.
- Competency is assessed using the six elements of competency for each test system:
  - Nonwaived testing – requires assessment of all six elements, as applicable to the duties performed.
  - Waived testing – program selects which elements to assess.
- Records of personnel competency assessment are retained.

Who Can Assess Competency?

Individuals assigned to assess competency must have the appropriate education and experience to evaluate the complexity of testing being assessed.

- Waived testing – qualifications of assessors may be determined by the laboratory director.
- Moderate complexity testing – must meet technical consultant qualifications*.
- High complexity testing – must meet general supervisor qualifications.

*If both moderate and high complexity testing is performed, a general supervisor or individual meeting those qualifications may assess the competency for both moderate and high complexity testing.

Who is Responsible?

The laboratory director is responsible for implementing and maintaining an effective competency assessment program.

Outcome of an Effective System

The laboratory benefits include:

- Ensuring employees are performing and recording laboratory tests and associated functions according to the laboratory procedures.
- Identifying problems with personnel performance to limit impact on patient care.
- Having processes to retrain and reassessing personnel when problems are identified.
- Maintaining ongoing compliance with CAP requirements.

QUALITY MANAGEMENT SYSTEM (QMS)

What is a Quality Management System?

A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services. A dynamic QMS enhances all activities that impact patient care, promoting quality and patient safety through risk reductions and continuous improvement.

Overview

Each laboratory must design and implement a QMS to include components that accurately reflect the operations of the laboratory. The QMS must cover:

- All areas of the laboratory and beneficiaries of service.
- All inherent processes, including core and support processes and procedures, procedures for monitoring processes, and procedures for improving processes.

Key Components

QMS components include:

- A document that describes the overall framework of the QMS and the patient care and client services offered by the laboratory.
- A process for identifying and recording non-conforming events.
- A process for investigation of non-conforming events, including root cause analysis for sentinel events.
- A system for monitoring key indicators of quality in the preanalytic, analytic, and post analytic phases of testing and comparing performance to laboratory-defined targets.
- A process for recording corrective and preventive actions taken for non-conforming events, quality indicators that do not meet defined targets, and evaluating the effectiveness of actions taken.
- A process for employees and patients to communicate quality and safety concerns to management.
- A process to assess the implementation of the QMS at least annually for effectiveness.
- An infrastructure for the quality management system, including aspects such as a document control system.

Who is Responsible?

The laboratory director is responsible for the implementation of the QMS with assistance and involvement from the:

- Manager
- Supervisor
- Laboratory staff
- Non-laboratory staff (eg, hospital quality assurance coordinator or safety and regulatory personnel)

Outcome of an Effective System

The laboratory benefits include:

- Continually ensuring that practice matches policies and procedures.
- Providing opportunities for quality improvement.

- Improving patient and/or clinician satisfaction.
- Maintaining ongoing compliance with CAP requirements.