COLLEGE of AMERICAN PATHOLOGISTS

Master

Director Assessment (DRA) Checklist

CAP Accreditation Program

College of American Pathologists
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Director Assessment (DRA) Checklist

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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES
Director Assessment (DRA) Checklist
12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged**:**
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

Requirement	Effective Date
DRA.10432	12/26/2024
DRA.10433	12/26/2024

REVISED Checklist Requirements

Requirement	Effective Date
DRA.10100	12/26/2024
DRA.10150	12/26/2024
DRA.10435	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements
None

UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

All checklist requirements contain a requirement number, subject header, phase, and a declarative statement. Some requirements also contain the following:

- Policy/Procedure Icon:
  - The placement of the icon next to a checklist requirement indicates that a **written policy or procedure is required to demonstrate compliance with the requirement.**
  - The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.
- NOTE:
  - Additional detail used to assist in interpreting the requirement. Information in the NOTE is considered integral to the requirement and must be complied with as part of the declarative statement itself, unless it is expressed as a recommendation or best practice.
- Evidence of Compliance (EOC):
  - A listing of suggested ways to demonstrate compliance with the requirement; some elements are required.

The Master version of the checklist also contains references and the inspector R.O.A.D. instructions (Read, Observe, Ask, Discover), which can provide valuable insight for the basis of requirements and on how compliance will be assessed.

INTRODUCTION

The Director Assessment Checklist, formerly known as the Team Leader Assessment of Director & Quality Checklist (TLC), emphasizes the role of the laboratory director and fulfillment of the laboratory director responsibilities. The checklist is used primarily by the team leader to perform a peer assessment of the laboratory director's role in ensuring laboratory quality.

When the term "laboratory director" is used, it refers to the individual who is listed on the laboratory's CAP and CLIA certificate (as applicable). Laboratory directors may delegate tasks to other qualified individuals, but the laboratory director retains full responsibility for such tasks. Delegation does not negate the need for laboratory director involvement in the laboratory.

When the term "patient" is used within a checklist, it may also refer to donors, clients, and study participants.


Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

***Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

INSTRUCTIONS

This checklist must be completed by the team leader or a team member who is qualified and trained to be a team leader. It is used to evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the Standards of the Laboratory Accreditation Program, including the laboratory's quality management system (QMS). It is also used to identify major or systemic deficiencies detected during the inspection that reflect lack of director oversight in areas such as QC, QM, proficiency testing, employee qualifications and records, competence and training, and the maintenance of a safe work environment.

If major or systemic deficiencies are identified during the inspection, cite the related requirement from this checklist as a deficiency and elaborate on the findings in the Inspector's Summary Report, Part A (ISR-A).

The following activities provide the information needed to complete the requirements in this checklist:

- ***Interview the laboratory director, supervisory personnel and other laboratory personnel as appropriate***
- ***Observe the operation of the laboratory***
- ***Review the laboratory organizational chart, quality management system (QMS) document and records, committee minutes, and other relevant documents for appropriate director involvement***
- ***Interview the hospital administrator, or an executive from the organization if the laboratory is an independent organization***
- ***Interview the chief of the medical staff or a representative (for laboratories associated with a medical staff)***
- ***Discuss deficiencies with members of the inspection team to assess their extent and determine if they directly affect patient safety, or are pervasive in the laboratory, which may warrant a deficiency in the Director Oversight Responsibilities section of this checklist.***

Interviews with the laboratory director, hospital or organization administrator, and representative of the medical staff are essential parts of the inspection. If for any reason one of these interviews was not performed, discuss the circumstances in the Inspector's Summation Report.

Meeting with the Laboratory Director

Purpose: *To help determine if the laboratory director has sufficient responsibility and authority for operation of the laboratory. Allow a minimum of 15-20 minutes for the meeting.*

The interview is an opportunity to:

- *Evaluate the director's activities as listed in the Standards for Laboratory Accreditation*
- *Review any problems that the inspection experience might serve to resolve (eg, space problems, staffing shortages)*
- *Determine whether the laboratory director also functions as a technical supervisor, clinical consultant, general supervisor, or testing personnel.*

Meeting with the Organization/Hospital Administrator/Chief Executive Officer (CEO)

For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Allow at least 15-20 minutes for the meeting. Avoid scheduling the meeting early in the inspection to have a sense of the laboratory's operations first. For independent laboratories, meet with an executive from the laboratory organization.

Purpose: *To extend the College's appreciation for participating in the accreditation program, to record an evaluation of the laboratory from the administration's viewpoint, and help assess the director's involvement in the administration of the laboratory.*

Points to communicate during the interview are:
- *The goals of the CAP Laboratory Accreditation Program: education and laboratory improvement; establishing best practices in laboratory medicine, based on input from national experts*
- *The inspection process: two-year accreditation cycle; use of active laboratorians as inspectors; educational value to inspector and inspected laboratory*
- *The role of proficiency testing in the program*
- *The role of the laboratory director and responsibility for the overall operation of the laboratory, under the requirements of the CAP 's accreditation programs.*

The interview is an opportunity to:
- *Ascertain the administration's perception of the laboratory service*
- *Discuss administration's view of the laboratory director's role in ensuring high quality laboratory services to fulfill the needs of the institution's patients and clinicians*
- *Determine if the institution gives the director the authority to fulfill the director's responsibilities under CAP*
- *Address the effectiveness of the working relationship among the laboratory, its director and administration*
- *Identify any areas of conflict.*

Discuss all laboratories being inspected. Do not discuss any financial and/or contractual arrangements.

When speaking with the hospital administrator, ask if the laboratory service level is appropriate to the needs of the institution. Ask how the pathologists participate in hospital-wide committees, how effective they are in working with the medical and administrative staffs, and whether they meet the expectations of the administration.

Record key findings from this interview in Part A of the Inspector's Summation Report.

Meeting with a Representative of the Medical Staff

For laboratories associated with organized medical staff, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer, or a physician who uses the laboratory's services frequently).

Allow for a 15-20 minute discussion, and come prepared with a general understanding of the laboratory's operations beforehand.

Purpose: *To determine whether the director and the laboratory staff have established an effective working relationship with the medical staff and are effectively supporting patient care.*

The interview is an opportunity to:
- *Evaluate how effectively the scope, quality, and timeliness of laboratory services meet the patient care needs of the hospital*
- *Assess the contribution of the pathologist and laboratory staff to teaching conferences and meetings*
- *Determine the cooperation of medical staff and pathologist in problem resolution*
- *Judge the medical community's perception of the effectiveness of the laboratory director and other pathologists, and determine if the laboratory director has sufficient authority to fulfill the needs of the medical staff and patients.*

When meeting with the chief or other active member of the medical staff, ask questions about the scope, quality and timeliness of laboratory services. The team leader should ask the medical staff representative for input on pathologist participation in medical staff committees, participation in institutional QMS and patient safety activities, and participation in teaching conferences. Include all laboratories being inspected, including special function and satellite laboratories.

The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Pre-Summation Conference

Prior to the summation conference, allow 30-60 minutes to meet privately as a group with the inspection team members to discuss and record inspection findings. The goal of the meeting is to ensure that both verbal and written inspection reports are complete and consistent. During the meeting:

- *Resolve team members' questions*
- *Ensure consistency in recording similar findings (eg, deficiency versus recommendation)*
- *Identify serious deficiencies that may jeopardize patient care and systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections*
- *Review the Part A Questions in the Inspector's Summation Report.*

If serious deficiencies or systemic issues are identified or any question from Part A is answered "NO," cite the appropriate checklist requirements relating to the issue and the DRA Checklist requirement for the laboratory director responsibility.

Common examples include:

Issue Observed	***Related DRA Requirement***
Lack of laboratory director involvement	*DRA.10435*
QMS not properly implemented	*DRA.10440*
Lack of thoroughness of the self-inspection and/or inadequate or untimely correction of deficiencies noted during the self-inspection process	*DRA.10445*
Inconsistent quality control/lack of corrective action	*DRA.10460*
Improper handling of proficiency testing materials/lack of follow-up for unacceptable results	*DRA.10460*
Lack of validation/verification records for new tests or instruments	*DRA.10475*
Insufficient numbers of personnel or incomplete records for personnel qualifications and/or training	*DRA.11300*
Unsafe laboratory practices compromise the safety of personnel	*DRA.11400*
Incomplete records for delegation of duties or duties not effectively carried out by designee(s) (eg, competency assessments not performed as required by designee) or delegation of functions to individuals who lack the necessary qualifications	*DRA.11425*

Summation Conference

Citations in this checklist are optional for discussion at the summation conference to which laboratory staff, hospital administration, and others may be invited. The team leader may instead choose to discuss them with the laboratory director in a private summation meeting.

DEFINITION OF TERMS

Addendum - Information appended to a final report with no changes to the original test result(s); original report is intact and unchanged, the addendum is added as an attachment or supplement to the original report.

Alternative performance assessment - A system for determining the reliability of laboratory examinations for which no commercial proficiency testing products are available, are not appropriate for the method or patient population served by the laboratory, or participation is not required by the accrediting organization.

Amended/amendment - Any change in a previously issued anatomic pathology or cytopathology report intended to correct an inaccuracy, including changes in the diagnosis, narrative text, clinical history, pre- and post-operative diagnoses, patient identification, or other content.

Analytical performance characteristics - For a specific test, the properties of a test identified from data collected during analytical validation or analytical verification studies.

Analytical validation - The process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

Analytical verification - The process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

Annual - Every 12 calendar months.

Authority - The power to give orders or make decisions: the power or right to direct someone or control a process.

Biennial - Every 24 calendar months.

Biorepository - An entity that collects, processes, stores, manages, and distributes biospecimens for research purposes. The term laboratory may also be used in the checklist to generically refer to a biorepository participating in the CAP's Biorepository Accreditation Program.

Calculated test result - A reportable patient test result that is not directly measured but rather calculated from one or more directly measured results.

Check - Examination to determine the accuracy, quality or presence of any attribute of a test system.

Clinical performance characteristics - For a specific test, the properties of a test identified from data collected during studies of clinical validation, clinical utility, or clinical usefulness.

Clinical validation - The determination of the ability of a test to diagnose or predict risk of a particular health condition or predisposition, measured by sensitivity, specificity, and predictive values.

Commutable - The property of a reference material that yields the same numeric result as would a patient's specimen containing the same quantity of analyte in the analytic method under discussion (ie, matrix effects are absent).

Confirmation - Substantiation of the correctness of a value or process.

Corrected/correction - A change in a previously issued clinical pathology test report intended to correct an inaccuracy, including changes in test results, patient identification, reference intervals, interpretation, or other content.

Corrective Action - Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Correlation - Establishment of a relationship between two or more measured values.

Credentialing - The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care in a health care organization.

Device - Any reagent, reagent product, kit, instrument, apparatus, equipment or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human specimens.

Digital image analysis - The computer-assisted software detection or quantification of specific features in an image following enhancement and processing of that image, including analysis of immunohistochemistry samples, DNA analysis, morphometric analysis, and in situ hybridization.

Distributive testing - Laboratory testing performed on the same specimen, or aliquot of it, that requires sharing between two or more laboratories (with different CLIA/CAP numbers) to provide a final, reportable result for the originally-ordered test. The laboratories involved may perform separate steps of "wet" testing, or may perform calculations, data analysis/informatics processing, or interpretive processes; all such models fall under the term distributive testing.

Equipment - Single apparatus or set of devices or apparatuses needed to perform a specific task.

Examination - In the context of checklist requirements, examination refers to the process of inspection of tissues and samples prior to analysis. An examination is not an analytical test.

External quality control - A stable material designed to simulate a patient specimen for monitoring the performance of a test procedure or system to ensure reliable results. Common examples include positive and negative liquid materials or swabs provided with test kits; assayed and unassayed liquid controls provided by an instrument manufacturer, third party supplier or prepared by the laboratory; and control slides purchased or prepared by the laboratory to demonstrate appropriate reactivity or staining characteristics. In contrast to internal quality control processes, external quality control materials are not built into the performance of the clinical assay. External quality control materials are not to be confused with external quality assessment (EQA) program materials (external proficiency testing).

FDA - 1) For laboratories subject to US regulations, FDA refers to the US Food and Drug Administration, which is the regulatory body under Health and Human Services (HHS) with authority to regulate *in vitro* diagnostic products such as kits, reagents, instruments, and test systems; 2) For laboratories not subject to US regulations, FDA refers to the national, state or provincial, or local authority having jurisdiction over *in vitro* diagnostic test systems.

Function Check - Confirmation that an instrument or item of equipment operates according to manufacturer's specifications prior to initial use, at prescribed intervals, or after minor adjustment (eg, base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

High complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health. Tests in this category are seen to have the highest risks to public health.

Instrument - An analytical unit that uses samples to perform chemical or physical assays (eg, chemistry analyzer, hematology analyzer).

Instrument platform - Any of a series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models.

Internal quality control - Processes integrated into the testing instrument and/or test system designed to monitor the performance of a test to ensure reliable results. Internal quality control may include electronic, built-in, or procedural control systems. On instruments/test systems with internal QC processes, performing the internal QC is typically a physical requirement of performance of the assay on clinical specimens.

Laboratory - Term used to refer to a clinical laboratory, biorepository, forensic drug testing laboratory, or reproductive laboratory participating in the CAP accreditation programs.

Laboratory Director - The individual who is responsible for the overall operation and administration of the laboratory, including provision of timely, reliable and clinically relevant test results and compliance with applicable regulations and accreditation requirements. This individual is listed on the laboratory's CAP and CLIA certificate (as applicable).

Maintenance - Activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, lubrication, electronic checks, or changing parts, fluids, or tubing, etc.

Moderate complexity - Rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health.

Modification of manufacturer's instructions - Any change to the manufacturer's supplied ingredients or modifications to the assay as set forth in the manufacturer's labeling and instructions. It may include a change to specimen type, instrumentation or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results.

For laboratories subject to US regulations, this includes modifications to FDA-cleared/approved tests. For laboratories not subject to US regulations, it also includes modifications to tests approved by an internationally recognized regulatory authority (eg, CE marking).

Non-conforming event - An occurrence that: 1) deviates from the laboratory's policies or procedures; 2) does not comply with applicable regulatory or accreditation requirements; or 3) has the potential to affect (or has affected) patients, donors, the general public, or personnel safety.

Nonwaived - Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity according to a scoring system used by the FDA.

Pathologist - A physician who has successfully completed an approved graduate medical education program in pathology.

In the US, a physician is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine who is licensed by the state to practice medicine, osteopathy, or podiatry within the state in which the laboratory is located. In jurisdictions not subject to US regulations, a physician is defined as an individual who has a primary medical school degree (eg, MBBS, MBChB, MD, DO) in keeping with the standards of that particular jurisdiction.

Performance verification - The set of processes that demonstrate an instrument or an item of equipment operates according to expectations prior to initial use and after repair or reconditioning (eg, replacement of critical components).

Personnel - The collective group of employees and contractors employed by the laboratory organization. Contractors may include those individuals contracted by the laboratory, such as pathologists, clinical or medical laboratory scientists, medical technologists, and non-laboratory individuals, such as respiratory therapists or nurses who perform patient testing. It would not include those individuals contracted outside the authority of the laboratory, such as medical waste disposal contractors, instrument service representatives, or cleaning contractors.

Policy - Written statement of overall guidelines, strategy, approach, intentions and directions endorsed by laboratory leadership that direct or restrict a facility's plans, actions, and decisions.

Predictive marker - Biomarker used independent of histologic findings to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy, compared to individuals with the same diagnosis lacking the biomarker.

Preventive action - Action taken to eliminate the cause of a potential nonconformity or any other undesirable potential situation.

Primary source verification report - A document, usually prepared by a third party agent or company that confirms that a job applicant's degree, certificate, or diploma is authentic, licenses were granted, and reported work history (company names, locations, dates and positions held) is accurate. The confirmation is obtained through direct contact with an institution, former employer, or their authorized agents.

Primary specimen - The body fluid, tissue, or sample submitted for examination, study or analysis. It may be within a collection tube, cup, syringe, swab, slide, data file, or other form as received by the laboratory.

Procedure - Set of specific instructions that describe the stepwise actions taken to complete a process, operation, activity, or task.

Process - 1) A set of related tasks or activities that accomplishes a work goal; 2) A set of interrelated or interacting activities that transforms inputs into outputs.

Proficiency testing - Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons. In some countries, the PT programs for clinical laboratories are called "external quality assessment" programs.

Qualified pathologist - A pathologist who has training in the specific functions to be performed (eg, an anatomic pathologist for anatomic pathology functions, a clinical pathologist for clinical pathology functions, or an anatomic pathologist or dermatopathologist for skin biopsies).

Quality management system (QMS) - A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.

Reagent - Any substance in a test system other than a solvent or support material that is required for the target analyte to be detected and its value measured in a sample.

Reference interval - The range of test values expected for a designated population of individuals.

Report errors - A report element (see GEN.41096) that is either incorrect or incomplete.

Responsibility - A duty or task that an individual is required or expected to do.

Root cause analysis (RCA) - A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.

Scope of Service - The scope of service is the description of the tests/services that the laboratory provides to its customers/clients (eg, tests offered, hours of operation, turnaround times).

Secondary specimen - Any derivative of the primary specimen used in subsequent phases of testing. It may be an aliquot, dilution tube, slide, block, culture plate, reaction unit, data extract file, image, or other form during the processing or testing of a specimen. (The aliquots or images created by automated devices and tracked by internal electronic means are not secondary specimens.)

Section Director - The individual who is responsible for the technical and/or scientific oversight of a specialty or section of the laboratory.

Semiannual - Every 6 calendar months.

Sentinel event - An unexpected occurrence that reaches a patient and results in death, permanent harm, or severe temporary harm, unrelated to the natural cause of the patient's illness or underlying condition.

Subject to US Regulations - Laboratories located within the United States and laboratories located outside of the US that have obtained or applied for a CLIA certificate to perform laboratory testing on specimens collected in the US and its territories for the assessment of the health of human beings.

Telepathology - The practice of pathology and cytology in which digitized or analog video, still image(s), or other data files are examined and an interpretation is rendered that is included in a formal diagnostic report in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record.

Test - A qualitative, quantitative, or semiquantitative procedure for detecting the presence of, or measuring of an analyte.

Testing personnel - Individuals responsible for performing laboratory assays and reporting laboratory results.

Test system - The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Visitor - An individual entering the laboratory who is not considered personnel.

Waived - A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result." Laboratories performing waived tests are subject to minimal regulatory requirements.

LABORATORY DIRECTOR ASSESSMENT

Inspector Instructions:

- Laboratory director’s qualifications
- Laboratory director's licensure as applicable
- Laboratory director’s job description, policy or agreement for director activities
- Laboratory director’s record of delegation of responsibilities
- Organizational chart
- Records of laboratory director activities and frequency of on-site visits. Ensure actual practice matches policy or agreement.
- Records of on-site assessment of physical and environmental conditions and the adequacy of staffing by the laboratory director

- Interaction of laboratory director with laboratory supervisory personnel and laboratory staff
- Technical staff recognition of the role and involvement of the laboratory director in setting expectations and service needs

Laboratory Director:

- What quality improvement initiatives have been most successful during the past two years? Which are works in progress?
- What educational programs have been made available to staff during the past two years?
- Have you had any complaints that would indicate that the laboratory is perceived as an unsafe working place for personnel and the patients it serves?
- How did your laboratory conduct the mid-cycle self-inspection?
- How do you ensure that the laboratory meets the expectations of hospital administration and medical staff?
- When was the last time your laboratory provided an inspection team? How did you ensure that all team members were trained?
- How do you ensure that the laboratory has adequate numbers of properly trained staff?
- How is your laboratory's QMS designed?
- How is the laboratory's QMS implemented in each section of the laboratory?

Organization Administrator:

- What level of involvement do pathologists have in organization-wide committees?
- How does the laboratory communicate important laboratory information to administration?
- How well does the laboratory meet the operational and clinical needs of the organization?

Medical Staff Representative:

- How is the laboratory involved in hospital-wide QMS activities, including patient care improvements, patient safely activities, and teaching conferences?
- What level of involvement do pathologists have in medical staff committees?
- How does the laboratory communicate important laboratory information to medical staff?
- How well does the laboratory meet the patient care needs (TAT, accuracy, responsiveness) of the organization?

DISCOVER	• If the administrator and/or the medical staff representative gave examples indicating that the laboratory did not meet their expectations, further evaluate laboratory leadership's responses, corrective actions and resolutions. • If QC failures are identified, determine whether they reflect systemic problems or involve patient safety. If so, was the laboratory director involved in the resolution? • Evaluate the laboratory director's involvement in key quality processes (proficiency testing, root cause analysis, procedure manual review, etc.) • Discuss the review of the interim self-inspection records with the Laboratory General inspector to identify issues with lack of thoroughness of the interim self-inspection or systemic problems identified during the self-inspection that have not been corrected. • Determine if there was a change of laboratory director within the last two years. If yes, confirm that the new laboratory director approved technical policies and procedures within three months of the change or that an explanation was recorded with a reasonable schedule for completion of the approval process.

QUALIFICATIONS AND GENERAL REQUIREMENTS

***REVISED** 12/26/2024*

DRA.10100 Laboratory Director Qualifications **Phase II**

The laboratory director satisfies the personnel requirements of the College of American Pathologists.

NOTE: The qualifications required by the CAP for the position of laboratory director depend on the testing performed in the laboratory. The qualifications are also dependent upon whether the laboratory is subject to US regulations.

The following table contains the laboratory director qualifications based on complexity of testing and US regulatory status:

Laboratories Subject to US Regulation	
Complexity of Testing	Qualifications
1. High complexity testing	a. MD, DO, or DPM licensed to practice in the jurisdiction where the laboratory is located (if required), **and**: i. Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, **or** ii. Have at least two years of experience supervising high complexity testing; **and** have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist* **OR** b. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and:** i. Have **current** certification by a board approved by HHS**, **and** ii. Have at least two years of laboratory training or experience or both, and

	laboratory experience directing or supervising high complexity testing **and** iii. Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in the DRA checklist*
2. Moderate complexity testing	a. Qualified as in (1) above **OR** b. MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), **and**: i. At least one year of experience supervising nonwaived laboratory testing, **and** ii. Have at least 20 CE credit hours in laboratory practice that cover director responsibilities as defined in the DRA checklist **OR** c. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution, **and**: i. Have current certification by a board approved by HHS**, **and** ii. Have at least one year of experience directing or supervising nonwaived testing, **and** iii. Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in the DRA checklist*
3. Provider-performed microscopy (PPM)	a. MD, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required)
4. Waived tests	a. MD, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required) **OR** b. Doctoral degree (PhD or DPH) in a chemical, biological, or clinical laboratory science from an accredited institution
Laboratories not subject to US regulations	
All Complexity Levels	a. MD or DO licensed to practice in the jurisdiction where the laboratory is located (if required) **and** have **one** of the following: i. Certification in anatomic or clinical pathology; or ii. At least one year of laboratory training during medical residency/fellowship; or iii. At least two years of experience supervising high complexity testing **OR** b. Doctoral degree (PhD, DPH, or equivalent) in a chemical, biological, or clinical laboratory science **and** have **both** of the following:

	i. At least two years of clinical laboratory training or experience **and** ii. Two years of laboratory experience directing or supervising high complexity testing

**This does not apply to existing laboratory directors that have remained continuously employed in their current role since December 28, 2024.*

***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 (no including laboratory 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 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.*

Evidence of Compliance:

- ✓ Records of director qualifications appropriate to the type of laboratory and level of complexity

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1405], [42CFR493.1407] and [42CFR493.1443].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):1049 [42CFR493.1357]
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):979 [42CFR493.19]
4) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.
5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1): [42CFR493.1445(d)].

DRA.10125 Director Qualifications - Biorepositories Only — Phase II

The qualifications of director of the biorepository are appropriate for the scope of activities.

NOTE: The director must have had four or more years of full-time general laboratory training and experience of which at least two years were spent acquiring proficiency in biorepository operations and management. The director must be qualified to assume professional, scientific, organizational, administrative, and educational responsibilities for the services provided. The director's experience and qualifications must also meet the institutional policy for the degree of responsibility acceptable to operate and manage the scope of the biorepository.

*****REVISED** 12/26/2024***

DRA.10150 Provision of Anatomic Pathology (AP) Services — Phase II

Anatomic pathology services are provided by a pathologist certified in anatomic pathology. Exceptions for other qualified individuals for specific subspecialties are described in the NOTE.

NOTE: In facilities where anatomic pathology services are provided, a pathologist certified in anatomic pathology must perform such services. Pathologists who qualified to provide these services prior to December 28, 2024, may continue to provide these services if they have done so continuously in a CLIA-certified laboratory. The services of a consulting anatomic pathologist shall be retained if necessary.

The following are exceptions for specific types of tissue diagnosis for non-pathologist individuals:

- *Neuromuscular pathology specimens may be interpreted by an MD or DO who is licensed to practice in the jurisdiction where the laboratory is located (if required) and has completed a training program in neuromuscular pathology approved by HHS (ie, the American Academy of Neurology Committee for Neuromuscular Pathology Training Program).*
- *Other exceptions for dermatopathology, ophthalmic pathology and oral pathology as defined in the CLIA regulation 42CFR493.1449(f) and (g).*

***For laboratories not subject to US regulations**, individuals must meet national, state or provincial, or local laws and regulations, and education must be equivalent to US qualifications.*

Evidence of Compliance:

- ✓ Listing of AP services provided by the institution **AND**
- ✓ Records of pathologist qualifications (eg, degree, license, board certification, training and experience)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1449(f)(g)].

DRA.10200 Section Director/Technical Supervisor Qualifications — Phase II

If the laboratory director is not qualified to direct any of the individual sections of the laboratory, the laboratory retains the services of individuals qualified to direct those sections.

Evidence of Compliance:

- ✓ Records of section director qualifications (eg, degree, license, board certification, training and experience)

LABORATORY DIRECTOR RESPONSIBILITY AND OVERSIGHT

NOTE TO THE INSPECTOR: Appropriate checklist requirements in this subsection should be cited if the inspection reveals serious deficiencies that may impact patient care or systemic problems where inspectors cited the same or related deficiencies in multiple laboratory sections. If the Team Leader marks "NO" to any of the Part A questions in the Inspector's Summation Report, one or more related DRA requirements must also be cited.

When the term laboratory director is used, it refers to the individual who is listed on the laboratory's CAP and CLIA certificate (as applicable). Laboratory directors may delegate tasks to other qualified individuals, but the laboratory director retains full responsibility for such tasks. Delegation does not negate the need for laboratory director involvement in the laboratory.

The requirements for laboratory director responsibilities apply to all laboratories. Laboratory directors must ensure that all laboratory director responsibilities are carried out as required. Refer to DRA.11425 for information on delegation of duties and duties that may not be delegated.

DRA.10430 Director Responsibility/Authority **Phase II**

The laboratory director has sufficient responsibility and authority to implement and maintain the standards of the College of American Pathologists.

NOTE: Examples of how the team leader may obtain information on the laboratory director's responsibility and authority include: interviews with the laboratory director, institution's administration, medical staff, laboratory management and laboratory supervisory staff; review of the laboratory organizational chart; and review of minutes of quality management and other laboratory meetings.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1407], [42CFR493.1443].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

*****NEW** 12/26/2024***

DRA.10432 Director On-Site Visits - Laboratories Subject to US Regulations **Phase II**

For laboratories subject to US regulations, on-site laboratory director visits occur at least every six months (with at least four months between the two on-site visits).

NOTE: This requirement applies when the laboratory director is not routinely on site. On-site visits must, at minimum, occur at the frequency described above. More frequent visits may be defined based on input from the medical staff and administration, and upon the complexity and volume of testing.

The requirement for on-site visits pertains to only one location site visit per CLIA certificate. The laboratory director may determine which site needs to be included during each on-site visit.

Records of on-site visits must include evidence that activities were performed that are part of the laboratory director responsibilities (eg, assessment of physical environmental conditions and adequacy of staffing).

Evidence of Compliance:

- ✓ Records of laboratory director activities for on-site visits **AND**
- ✓ Records for frequency of on-site visits **AND**
- ✓ Document defining frequency for on-site visits

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1445(c)].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1407(c)].

*****NEW** 12/26/2024***

DRA.10433 Director On-Site Visits - Laboratories Not Subject to US Regulations **Phase II**

For laboratories not subject to US regulations, on-site laboratory director visits occur at least once per year.

NOTE: This requirement applies when the laboratory director is not routinely on site. On-site visits must, at minimum, occur at the frequency described above. More frequent visits may be defined based on input from the medical staff and administration, and based upon the complexity and volume of testing.

The requirement for on-site visits pertains to only one location site visit per CAP-accredited laboratory. The laboratory director may determine which site needs to be included during each on-site visit.

Records of on-site visits must include evidence that activities were performed that are part of the laboratory director responsibilities (eg, assessment of physical environmental conditions and adequacy of staffing).

Evidence of Compliance:

- ✓ Records of laboratory director activities for on-site visits **AND**
- ✓ Records for frequency for on-site visits **AND**
- ✓ Document defining frequency for on-site visits

*****REVISED** 12/26/2024***

DRA.10435 Director Involvement **Phase II**

The involvement of the laboratory director, including activities performed on-site and through remote consultation, is considered adequate by the laboratory administration, medical staff, and the inspection team, and follows written policy or agreement.

NOTE: The laboratory director must ensure that there is an effective communication mechanism between the laboratory director and medical staff, laboratory management, and staff, including maintenance of records of the communications.

Examples of situations where director involvement is insufficient include the following:

- *Laboratory director does not perform duties as defined in the job description, policy or written agreement;*
- *Unsatisfactory availability of consultation services concerning test results and the interpretation of those results as they relate to specific patient conditions;*
- *Serious quality, personnel, or safety issues are not addressed in a timely manner;*
- *Delegated duties are not being performed and recorded, or are not performed in an effective manner;*
- *New laboratory practices are not implemented properly;*
- *Interviews with the hospital administrator, the chief of staff, laboratory supervisors, or technical staff identify situations (eg, ineffective communication mechanisms) where greater personal involvement on the part of the laboratory director is needed.*

Evidence of Compliance:

- ✓ Records of laboratory director activities (on-site and remote) **AND**

- ✓ Meeting minutes showing director participation **AND**
- ✓ Laboratory director review of quality management records **AND**
- ✓ Evidence of availability for consultations with medical staff as appropriate (based on interview with medical and laboratory staff or records of consultations)

DRA.10437 Director's Responsibilities - Biorepositories Only **Phase II**

The biorepository director has implemented policies to ensure that:

1. **IRB protocols and policies are followed**
2. **HIPAA is not violated**
3. **Clinical care is not compromised in the process of procuring biospecimens**
4. **Basic ethical standards related to biospecimen collection and distribution are followed (eg, all tissues are handled following protocols)**

DRA.10440 Effective Quality Management System (QMS) **Phase II**

The laboratory director ensures an effective QMS for the laboratory.

NOTE: The laboratory director must be involved in the design, implementation and oversight of the laboratory's QMS as set forth in GEN.13806.

Evidence of Compliance:

- ✓ Written QMS covering all areas of the laboratory **AND**
- ✓ Records of laboratory director approval of the QMS and the selection of quality indicators **AND**
- ✓ Records (eg, reports, QMS meeting minutes) of laboratory director review of quality indicators, annual assessment of QMS, complaints, and incidents with development and implementation of plans of corrective and preventive action (when taken)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1407(e)(5-6), [42CFR493.1445(e)(5,13)].
2) Clinical and Laboratory Standards Institute (CLSI). A *Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3) College of American Pathologists. CAP Quality Management Education: QMS Implementation Roadmap (online course). 2021.

DRA.10445 Director Responsibility - Interim Self-inspection **Phase II**

The laboratory director ensures that a thorough interim self-inspection is performed, and all deficiencies are corrected in a timely manner.

NOTE: CAP-accredited laboratories are required to complete an interim self-inspection, using the CAP checklists, at the start of the second year of the laboratory's two-year accreditation cycle, unless an exception is granted by the CAP. It is an important aspect of continuing education, laboratory improvement, and continuous compliance. The use of a variety of mechanisms for self-inspection (residents, technologists or others trained to perform inspections) is strongly endorsed. Self-inspection by personnel familiar with, but not directly involved in, the routine operation of the laboratory section to be inspected is recommended.

Refer to the "Self & Post Inspection Toolbox" on cap.org behind e-LAB Solutions Suite for tips and forms that are available for conducting thorough self-inspections.

Examples of noncompliance include situations in which systemic deficiencies were not identified, self-inspection of more than one laboratory section was incomplete, repetitive patient or employee safety issues were not addressed, and correction of deficiencies was lacking.

Evidence of Compliance:

- ✓ Written evidence of self-inspection findings with records of corrective action

DRA.10460 Director Responsibility - PT/QC **Phase II**

The laboratory director ensures that proficiency testing, alternative performance assessment, and QC procedures are sufficient for the extent of testing performed in the laboratory.

Evidence of Compliance:
- ✓ Records of PT and alternative performance assessment data, investigation, and corrective action, as applicable **AND**
- ✓ Written QC procedures for all areas of the laboratory **AND**
- ✓ Records of laboratory director or designee review of QC and corrective actions **AND**
- ✓ Records of laboratory director or designee involvement when PT/QC problems directly affect patient care

DRA.10475 Director Responsibility - New Method Validation/Verification **Phase II**

The laboratory director ensures that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing.

NOTE: Specific requirements are in the All Common Checklist (Instruments & Equipment, Test Method Validation/Verification, and Method Performance Specifications sections) and in other checklists.

Artificial intelligence and machine learning algorithms implemented by the laboratory for patient testing are subject to this requirement.

Evidence of Compliance:
- ✓ Written procedures for validation/verification studies **AND**
- ✓ Records of new method validation/verification approval and supporting data

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1407(e)(3), [42CFR493.1445(e)(3)].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

DRA.10500 Director Responsibility - Communication **Phase II**

The laboratory director ensures communication of laboratory data and appropriate result reporting.

Evidence of Compliance:
- ✓ Records of oversight of computer services and changes **AND**
- ✓ Evidence that test reports have been reviewed within the medical record **OR**
- ✓ Lab communications, newsletters, etc.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(c), (e)(8,9)], [42CFR493.1445].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.

DRA.10700 Director Responsibility - Consultations **Phase II**

The laboratory director provides for intralaboratory consultations and clinical consultations regarding the ordering of appropriate tests and the medical significance of laboratory data.

NOTE: Only physicians or doctoral scientists may provide clinical consultations.

The laboratory director must be accessible to the laboratory for on-site, telephone, or electronic consultations, as needed, or ensure that a qualified designee is available in the director's absence.

Evidence of Compliance:

- ✓ Policy or call schedule for the availability of the laboratory director and designee(s) to provide consultations **AND**
- ✓ Policy or statement signed by the laboratory director authorizing individuals responsible for clinical consultations **AND**
- ✓ Records of laboratory director or designee involvement for the ordering of tests and/or interpretation of results **AND**
- ✓ Evidence of the availability of the laboratory director or designee for consultative services (based on interview with medical staff or records)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(8,9)], [42CFR493.1445].
2) College of American Pathologists. *CAP Laboratory Accreditation Program Standards for Accreditation.* Northfield, IL: CAP; 2023.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):1067 [42CFR493.1457]

DRA.11200 Director Responsibility - Education/R&D — Phase II

The laboratory director ensures provision of educational programs, strategic planning, and research and development appropriate to the needs of the laboratory and institution.

Evidence of Compliance:

- ✓ Schedule or description of available educational activities **AND**
- ✓ Records or minutes from strategic planning sessions demonstrating participation and role of laboratory director

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(12)], [42CFR493.1445(e)(12)].
2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

DRA.11300 Director Responsibility - Personnel — Phase II

The laboratory director ensures sufficient numbers of personnel with appropriate educational qualifications, documented training and experience, and adequate competency to meet the needs of the laboratory.

NOTE: For laboratories subject to US regulations, all personnel must meet the personnel requirements of CLIA or other US equivalent regulations (eg, Clinical Laboratory Improvement Program Procedures for Department of Defense laboratories, Veterans Health Administration Handbook 1106.01). For laboratories not subject to US regulations, all personnel requirements must be defined and met.

While the laboratory director must ensure provisions of appropriately trained supervisory and testing personnel, the laboratory director may delegate (in writing) many of the duties relating to hiring, training, and supervising personnel to other qualified designees.

Staffing should be considered insufficient if there is clear evidence from quality monitoring records, data derived from complaints or concerns, turnaround time, error statistics, etc.

Evidence of Compliance:

- ✓ Records indicating that personnel meet requirements for the level of testing (complexity) performed and delegated tasks are performed **AND**
- ✓ Records of training, competency assessment, and continuing education in personnel files **AND**
- ✓ Records of periodic on-site assessment of the adequacy of staffing by the laboratory director

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(10-11)], [42CFR493.1445(e)(12)].
2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

3) Boyd JC, Savory J. Genetic algorithm for scheduling of laboratory personnel. *Clin Chem.* 2001;47:118-123

DRA.11400 Director Responsibility - Safe Environment Phase II

The laboratory director ensures implementation of a safe laboratory environment in compliance with applicable regulations.

NOTE: The laboratory director must ensure compliance with OSHA and national, federal, state (or provincial), and local laws and regulations, as well as other applicable safety regulations. Details may be found in the Laboratory Safety and Specimen Transport and Tracking sections of the Laboratory General Checklist. Additional safety requirements may also be found in the discipline-specific checklists (eg, Microbiology Checklist, Anatomic Pathology Checklist).

Evidence of Compliance:

- ✓ Safety policies and procedures **AND**
- ✓ Records of safe work practice reviews with corrective action taken to correct violations **AND**
- ✓ Safety meeting minutes **AND**
- ✓ Chemical hygiene plan **AND**
- ✓ Records of periodic on-site assessment of physical and environmental conditions by the laboratory director

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1407(e)(2)], [42CFR493.1445(e)(2)].

DRA.11425 Director Responsibility - Delegation of Functions Phase II

If specific laboratory director functions or responsibilities are delegated, the delegation is in writing (by name or job title) and the director ensures that the functions or responsibilities are properly performed by a qualified individual.

NOTE:

1. *Examples of functions that may be delegated include the following:*
   - *Review of QC data*
   - *Proficiency testing performance*
   - *Competency assessment*
   - *Test methodology performance studies.*
2. *Functions that may <u>not</u> be delegated include the following:*
   - *Provision of appropriately trained supervisory and technical staff and the identification of their responsibilities*
   - *Personal on-site visits, including assessment of physical and environmental conditions and the adequacy of staffing on a periodic basis, as defined in written policy*
   - *Approval of new technical policies and procedures, as well as substantial changes to existing documents (except as defined in COM.10250 for laboratories not subject to US regulations)*
   - *Approval of individualized quality control plans (IQCP).*
3. *For CLIA-required roles not performed by the director, the director delegates those responsibilities to qualified individuals. The responsibilities and duties of supervisors, consultants, and testing personnel involved in preanalytic, analytic, and postanalytic phases of testing must be defined in writing, with records of authorization to perform testing, and the level of supervision required, as applicable.*
4. *If a delegated duty is not being properly performed by the designee and there is no evidence of corrective action, the team leader should cite this requirement as a deficiency, in addition to the specific checklist requirement(s) that relates to the duty not performed (eg, monthly QC review, approval of method validation/verification studies).*
5. *Delegated functions may not be sub-delegated to others by a designee except as specifically outlined in other requirements (eg, GEN.53400, GEN.53600).*

Evidence of Compliance:

- ✓ Personnel roster accurately indicates qualified individuals performing roles of testing personnel, clinical consultant, technical consultant, technical supervisor, and general supervisor, as applicable **AND**
- ✓ Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform tasks on behalf of the laboratory director **AND**
- ✓ Records showing that delegated tasks are performed by designee, as required **AND**
- ✓ Records of on-site assessment of physical and environmental conditions and the adequacy of staffing by the laboratory director **AND**
- ✓ Records showing that designees are qualified to perform delegated tasks

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28) [42CFR493.1407(e)(2)], [42CFR493.1445(e)(15)].

DRA.11450 Director Responsibility - Interaction with Government or Regulatory Interaction — Phase II

The laboratory director or designee interacts with government and other agencies as appropriate.

NOTE: The laboratory director or designee must interact with agencies such as national, federal, state (or provincial), and local health departments, as appropriate, for laboratory-related matters.

Evidence of Compliance:

- ✓ Records of any required reports of infectious diseases to the health department **AND**
- ✓ Response to any inquiry by government and other agencies, as appropriate **AND**
- ✓ Reports to OSHA, FDA or other agency, as required

DRA.11475 Director Responsibility - Equipment/Services — Phase I

The laboratory director or designee is directly involved in the selection of all laboratory equipment, supplies, and services with respect to quality.

NOTE: The intent is to ensure that the laboratory director has appropriate control over the process. The fact that economic issues are a major factor in these selections does not relieve the laboratory director of responsibility for ensuring the quality of the technical, clinical and operational aspects of the laboratory. The director must ensure that reagents, fluids, parts, materials, and other items supplied to the laboratory meet the requirements for use with instruments and equipment.

Evidence of Compliance:

- ✓ Meeting minutes indicating the laboratory director or designee's presence when purchases are discussed **OR**
- ✓ Written approval from the laboratory director or designee to purchase equipment

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(a)]

DRA.11485 New Director Policy and Procedure Approval — Phase II

Following a change in laboratory directorship, the new laboratory director approves the technical policies and procedures within three months of the change of directorship (see NOTE).

NOTE:

1. The approval of the policies and procedures must be recorded.

2. *The format of such documentation is at the discretion of the laboratory director. It must include an itemization of the documents reviewed and approved, signatures and dates, and demonstrate that all technical policies and procedures have been approved.*
3. *The approval must be completed within three months of the change of directorship for most laboratories. For larger, more complex laboratories where additional time is needed, the laboratory can record an explanation and a schedule for completion of the approvals by the laboratory director. The inspector will verify completion of the approval process for compliance with the schedule.*
4. *Different requirements for approval of new and substantially changed technical policies and procedures and for routine reviews (at least every two years) appear in the All Common Checklist.*

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28): [42CFR493.1251(d)], [42CFR493.1445(e)].