December 2024 Changes

COLLEGE of AMERICAN PATHOLOGISTS

Director Assessment (DRA) Checklist

CAP Accreditation Program

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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text**. Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.
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2024 CHECKLIST EDITION CHANGES
NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
		New	DRA	10432
		New	DRA	10433

*Deleted – Removed the requirement from the checklist edition
*Merged – Combined the requirement with a similar requirement in the same or different checklist
*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists ~~from the CAP website (cap.org)~~ 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.

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 ~~best practice or~~ 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).*

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 ~~agreement~~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 (~~e.g.~~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 (~~e.g.~~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 ~~in~~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 ~~testing - Immunohistochemical, immunocytochemical, and in situ hybridization tests~~ - Biomarker used ~~to predict responsiveness to a specific treatment~~ independent of ~~other histopathologic~~histologic findings~~. Rather than confirming a specific diagnosis, these tests differentiate predicted responsiveness to a~~ to identify individuals who are more likely to experience a favorable or unfavorable effect from a specific (targeted) therapy~~ among cases of~~, 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

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** ~~have **one** of the following~~: i. Certification in anatomic or clinical pathology, or both, by the American Board of Pathology or American Osteopathic Board of Pathology, **or** ~~possess qualifications equivalent to those required for certification**; or~~ ~~ii. Have at least one year of laboratory training during medical residency/fellowship; or~~

	~~iii.~~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, ~~physical,~~ biological, or clinical laboratory science from an accredited institution, **and** ~~have~~**:** 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** ~~have **one** of the following~~: ~~i. At least 20 hours of continuing medical education credit hours in laboratory medicine; or~~ ~~ii. Equivalent training during medical residency/fellowship; or~~ ~~iii.~~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, ~~physical,~~ biological, or clinical laboratory science from an accredited institution ~~with one of the following~~**, and**: ~~i. At least one year of experience supervising nonwaived laboratory testing; or~~ i. ~~**Current**~~Have current certification by a board approved by HHS~~***~~**, and** ii. Have at least one year of experience directing or supervising nonwaived testing, **and** ~~ii.~~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 ~~or~~, DO, or DPM, licensed to practice in the jurisdiction in which the laboratory is located (if required)
4. Waived tests	a. MD ~~or~~, 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, ~~physical,~~ 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~~, physical~~, 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

~~*For laboratories subject to US regulations, additional qualifications for grandfathered individuals and for the subspecialty of oral pathology may be found in the CLIA regulation 42CFR493.1443(b)(6).*~~

~~*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.*~~

**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 ~~onsite~~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 ~~laboratory~~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.*

~~***Individuals qualifying as board-eligible must supply a letter or other equivalent record from the board with their eligibility status.*~~
~~****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*~~

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.* ~~1992(Feb~~2023(Dec 28~~):7175~~):[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):1050 [42CFR493.1405]~~
~~3~~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]
~~4~~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]

~~5~~4) College of American Pathologists. ~~Standards for~~ *CAP Laboratory Accreditation*~~; Standard I.~~ *Program Standards for Accreditation.* Northfield, IL: CAP~~, 2021~~; 2023.
~~6~~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):~~1052 and 1057~~ [42CFR493.~~1407(d) and~~ 1445(d~~)]~~)].

***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 ~~or possessing qualifications equivalent to those required for certification~~. 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 ~~(or possessing qualifications equivalent to those required for certification) must perform such services.~~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(~~l~~f) and (~~m~~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, ~~current CV,~~ 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.* ~~2004(Oct 1):1059~~ 2023(Dec 28):[42CFR493.1449(~~l~~) 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, ~~current CV,~~ degree, license, board certification, training and experience)

***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: ~~If the activities are routinely conducted remotely, periodic on-site visits must occur at a frequency established with the medical staff and administration based upon complexity and volume of testing and must be defined in a written policy or agreement. On-site assessments of the physical and environmental conditions and the adequacy of staffing must occur on a periodic basis, as defined in written policy.~~

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**
~~✓ Records for frequency of on-site visits **AND**~~
✓ Evidence of availability for consultations with medical staff as appropriate (based on interview with medical and laboratory staff or records of consultations) ~~**AND**~~
~~✓ Document defining frequency for on-site visits~~

~~REFERENCES~~

~~1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #7. Clinical Laboratory Improvement Amendments (CLIA). Director Responsibilities, August 2006. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf. Accessed September 23, 2020.~~

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 not 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.* ~~1992(Feb~~2023(Dec 28) [42CFR493.1407(e)(2)], ~~7176~~[42CFR493.1445(e)(15)].
~~2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #7. Clinical Laboratory Improvement Amendments (CLIA). Director Responsibilities, August 2006. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf. Accessed September 23, 2020.~~