December 2024 Changes

COLLEGE of AMERICAN PATHOLOGISTS

Laboratory General Checklist

CAP Accreditation Program

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CAP inspections are performed with the edition of the Checklists mailed to a facility at the completion of the application or reapplication process, not necessarily those currently posted on the website. The checklists undergo regular revision and a new edition may be published after the inspection materials are sent.

For questions about the use of the Checklists or Checklist interpretation, email accred@cap.org or call 800-323-4040 or 847-832-7000 (international customers, use country code 001).

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.

2024 CHECKLIST EDITION CHANGES
NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement		Action Taken	2024 Requirement	
		New	GEN	41318

*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 Laboratory General (GEN) Checklist applies to all sections or departments of the laboratory. It is customized based on the services reported by the laboratory to the CAP on its application.

One copy of the GEN Checklist is provided to the inspection team. One or more inspectors may be assigned to inspect with the GEN Checklist; however, all inspectors must be familiar with the GEN Checklist requirements and ensure that all areas are in compliance.

The use of the term "patient" within checklist requirements when referring to specimens, records, testing, reports, and other required elements is intended to apply broadly to the population served by the laboratory and may also include 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).*

Requirements specifically designated as "biorepositories only" apply to laboratories participating in the CAP's Biorepository Accreditation Program and do not apply to laboratories in the CAP's other accreditation programs.

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.

QUALITY MANAGEMENT SYSTEM

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GEN.13806 Quality Management System (QMS) **Phase II**

The laboratory has a document that describes the overall QMS.

NOTE: The document can be based on an existing model such as CLSI QMS01, ISO 9001, or ISO 15189, or may be the laboratory's own design.

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

Each facility must design a QMS to include components that accurately reflect the operations of the laboratory. Examples of QMS components typically found in a laboratory's QMS are provided in the table below.

QMS Component	Examples
Core Process and Procedures	Preanalytical (eg, test ordering, specimen collection) Analytical (eg, testing results review, equipment validated, quality control) Postanalytical (eg, results reporting, archiving specimens)
Support Process and Procedures	Document Control Information Management Contacts/agreements with external vendors/suppliers Training

Procedures for Monitoring Processes	Analysis of quality indicators, quality control and proficiency testing results Assessment of interim self-inspections and external inspections (eg, inspections conducted by accrediting organizations)
Procedures for Improving Processes	Evaluation of feedback from clients/customers/employees Investigation of non-conforming events, including root cause analysis for sentinel events Evaluation of effectiveness of corrective actions taken of non-conforming events

If the laboratory is part of a larger organization, the laboratory QMS describes its process for communicating quality monitors or concerns appropriate for the organization's overall QM program. This process may include participation in a medical executive committee, the organization's quality management reporting structure, or direct interaction with other departments in the organization. Evidence of participation may include submission of data, minutes from the organizational QM activity, or records of standing meetings. Laboratory quality initiatives that may be reported through this process include, but are not limited to, unexpected post-operative diagnoses, blood component usage, or test ordering practices.

QMS document examples can be found on cap.org behind e-Lab Solutions Suite - Accreditation Resources - Quality Management.

Evidence of Compliance:

✓ Outline of overall QMS specific to the laboratory's operation **AND**

✓ Records of participation in the organizational QM program, if appropriate

REFERENCES

1) ISO Standards compendium: ISO 9001:2015, Quality management systems -- Requirements. Geneva, Switzerland: International Organization for Standardization, 2015
2) ISO 15189:~~2012~~2022 Medical laboratories ~~--~~ , Requirements for ~~quality~~Quality and ~~competence. Geneva, Switzerland:~~Competence. International Organization for Standardization~~, 2012~~ , 2022.
3) 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.
4) ~~Jhai~~Zhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017.
5) Valenstein P. Quality Management In Clinical Laboratories. Chicago, IL: CAP Press, 2005
6) Ned-Sykes R, Johnson C, Ridderhof JC, Perlman E, Pollack A, DeBoy JM; Centers for Disease Control and Prevention (CDC). Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories. *MMWR Suppl.* 2015:64(1).

GEN.20325 ~~Employee~~Personnel and Patient Quality Communication **Phase II**

The QMS includes a process for ~~employees~~personnel and patients to communicate quality and safety concerns to management with appropriate follow-up of such concerns.

Evidence of Compliance:

✓ Records of ~~employee~~personnel and patient complaints (if any) with appropriate follow up

GEN.20327 Quality Communication - Biorepositories Only **Phase II**

The quality management system includes a process for ~~employees~~personnel, participants, and researchers to communicate quality, safety, and research misconduct concerns to management with appropriate follow-up of such concerns.

NOTE: The investigation and analysis of ~~employee~~personnel, participant, and researcher complaints and suggestions, with corrective or preventive action as appropriate, must be included in the biorepository quality management records.

Evidence of Compliance:

✓ Records of ~~employee~~personnel, participant, and researcher complaints (if any) with appropriate follow up

GEN.20330 Quality Concerns - CAP Sign **Phase II**

The laboratory posts the official CAP sign regarding the reporting of quality concerns to the CAP in a prominent location in the laboratory.

NOTE: The sign is intended to be placed in a location where it will be available to personnel. It is not a requirement to post the CAP sign in patient care areas.

While personnel should report concerns to laboratory management, the laboratory must ensure that all personnel know that they may communicate with the CAP directly if they have a concern not addressed by laboratory management, and that the CAP holds such communications in strict confidence. In addition, the laboratory must have a policy prohibiting harassment or punitive action against personnel in response to a complaint or concern made to the CAP or other regulatory organization regarding laboratory quality or safety.

Laboratories new to the CAP's accreditation programs (not yet accredited) receive a temporary sign after completion of the online application process, which must be posted upon receipt. After laboratories are accredited, they are awarded with the official sign for CAP-accredited laboratories to replace the temporary sign.

The dedicated, confidential CAP telephone lines for quality or safety concerns are 866-236-7212 (US, toll-free) and 847-832-7533 (international).

Additional CAP signs may be obtained by contacting the CAP at 800-323-4040 or in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources.

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

GEN.20335 Customer Satisfaction **Phase I**

The laboratory has measured the satisfaction of clients (eg, healthcare providers, patients, referring laboratories, nurses) with laboratory services within the past two years.

NOTE: Satisfaction metrics are important for understanding the needs of clients to improve laboratory services. Experience has shown that surveys are more informative if ~~they are conducted anonymously and allow for~~ open ended comments are allowed and received in near real-time, including participant contact and/or location information, with an option to remain anonymous, so that issues that affect customers can be resolved by the laboratory staff.

Evidence of Compliance:

✓ Records of the design and results of satisfaction surveys

REFERENCES

1) Kiechle FL~~, Funk DM, Rossler R, Sesok-Pizzini D.~~, So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy, ~~14th~~15th edition. Northfield, IL: College of American Pathologists, ~~2014~~2017.
2) Steindel SJ, Howanitz PJ. Physician satisfaction and emergency department laboratory test turnaround time. Observations based on College of American Pathologists Q-Probes studies. *Arch Pathol Lab Med.* 2001;125:863-871
3) Howanitz PJ, Cembrowski GS, Bachner P. Laboratory phlebotomy: College of American Pathologists Q-Probes study of patient satisfaction and complications in 23783 patients. *Arch Pathol Lab Med* 991; 115:867-872.
4) Dale JC, Novis DA, Meier FA. Reference laboratory telephone service quality: College of American Pathologists Q-Probes study of 545 laboratories. *Arch Pathol Lab Med.* 2001; 125:608-612.
5) Zarbo RJ, Nakhleh RE, Walsh, M. Customer satisfaction in anatomic pathology: a College of American Pathologists Q-Probes study of 3065 physician surveys from 94 laboratories. *Arch Pathol Lab Med.* 2003; 127:23-29.

6) Jones BA, Walsh MK, Rudy SG. Hospital nursing satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 162 institutions. *Arch Pathol Lab Med.* 2006; 130:1756-1761.
7) Nakhleh RE, Souers R, Ruby SG. Physician satisfaction with surgical pathology reports: a 2-year College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2008; 132:1719-1722.
8) Jones BA, Bekeris LG, Nakhleh RE, *et al*. Physician satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 138 institutions. *Arch Pathol Lab Med.* 2009; 133:38-43.
9) Clinical and Laboratory Standards Institute (CLSI). 1st ed. *Customer Focus in a Quality Management System.* CLSI guideline QMS19. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.
10) Macdonald EK, Wilson HN, Konus U. Better customer insight - in real time. Harvard Business Review. 2012(9). Accessed January 6, 2023. https://hbr.org/2012/09/better-customer-insight-in-real-time
11) Jackson BR, Novis D, Coulter SN, Dintzis S, Blond BJ, Brown RW. Improving the Customer Experience: Physician Feedback Program for Clinical Laboratories. Published online September 11, 2023. *Arch Pathol Lab Med.* 2023.

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GEN.26791 Terms of Accreditation **Phase II**

The laboratory complies with the CAP terms of accreditation.

NOTE: The CAP terms of accreditation are listed in the laboratory's application for accreditation and in the official notification of accreditation. A laboratory that is accredited by the CAP or has applied for accreditation must have a written policy that includes:

- *Cooperation in any CAP investigation or inspection and **prompt notification** to the CAP if the laboratory becomes the subject of:*
  - *An investigation by a government entity (including national, federal, state (or provincial), local, or foreign) or by another accreditation organization*
  - *A validation inspection*
  - *Adverse media attention relating to laboratory performance*
- *Prompt notification to the CAP:*
  - *If the laboratory discovers laboratory personnel actions that appear to violate national, federal, state (or provincial), or local laws that regulate laboratories*
  - *Of any changes in laboratory activity menu prior to beginning that testing or implementing scope of service/analytic method changes, or the laboratory permanently or temporarily discontinues some or all testing*
  - *Of any changes in directorship, location, ownership, name, insolvency, or bankruptcy~~.~~ within two business days of the change. Laboratories subject to the US CLIA regulations must also notify the CMS of pertinent changes within 30 days of the change.*
- *Provision of a trained inspection team comparable in size and scope to that required for its own inspection during the two-year accreditation period, if requested by the regional and/or state commissioner*
- *If the laboratory is subject to the US CLIA regulations:*
  - *Availability, on a reasonable basis, the laboratory's annual PT results upon request of any person*
  - *Provisions to allow the CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operations and permit the CMS to monitor the correction of any deficiencies found during such an inspection*
- *Adherence to the Certificate Mark Terms of Use/Agreement for the CAP Certification Mark and Design if the laboratory is/or will use the CAP Certification Mark for accreditation. The agreement can be downloaded and printed from cap.org.*

Evidence of Compliance:

✓ Records of notification, if applicable

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GEN.30000 Monitoring Analytic Performance **Phase II**

The laboratory's quality control program clearly defines policies and procedures for monitoring analytic performance.

NOTE: There must be a written overall quality control program for the entire laboratory. It must include general policies and assignment of responsibilities. There must be clearly defined, written procedures for ongoing monitoring of analytic performance, including:

- *Appropriate controls*
- *Establishment of tolerance limits for control testing*
- *Corrective actions based on quality control data*

Quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director~~, supervisor or laboratory quality control coordinator).~~ or designee). Appropriate evidence of review includes both the reviewer's signature or initials and the review date.

SPECIMEN COLLECTION, HANDLING, AND REPORTING

BLOOD CULTURE SPECIMEN COLLECTION FOR REFERRAL ONLY

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

GEN.40560 Blood Culture Media QC **Phase II**

The laboratory inspects blood culture media shipments received from the referral laboratory and retains records of media quality control performed by the referral laboratory.

NOTE: The inspection of media is intended to identify problems with breakage, contamination, appearance, or evidence of freezing or overheating. Problems with blood culture media must be reported to the referral laboratory.

The referral (testing) laboratory must provide records or certification of media quality control with each shipment. If the referral laboratory uses an individualized quality control plan (IQCP) to allow for the acceptance of the quality control performed by the media supplier, the referring (collecting) laboratory receiving the media must obtain a copy of the applicable IQCP or IQCP summary statement ~~and retain records showing approval of the IQCP by~~(it is not necessary for the referral laboratory to provide the data used to develop the IQCP). The director ~~at~~of the ~~referring~~ laboratory receiving the media must approve the IQCP and retain the record to show acceptance of the media QC processes.

Evidence of Compliance:

✓ Records of media inspection and quality control **AND**
✓ Individualized quality control plan for the media, as applicable

REFERENCES
1) Clinical and Laboratory Standards Institute. *Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard;* 3rd ed. CLSI document M22-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2004.
2) 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): [42CFR493.1256(e)]

REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/PROCESSING

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

GEN.40750 Requisition Elements **Phase II**

All specimens are accompanied by a paper requisition or linked to an electronic requisition that includes the following elements, as applicable:

1. **Adequate patient identification information (eg, name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists)**
2. **Patient sex**
3. **Patient date of birth or age**
4. **Name and address (if different than the receiving laboratory) of the physician, legally authorized person ordering the test, or name and address of the laboratory referring the specimen**
5. **Tests requested**
6. **Last menstrual period (for all gynecological cytology specimens and other gynecologic specimens, when appropriate)**
7. **Date of specimen collection, and if appropriate, time of collection**
8. **Source of specimen, when appropriate**
9. **Clinical information, when appropriate**

NOTE: Specimen source may be particularly important for microbiology, surgical pathology, and cytopathology specimens. Surgical pathology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed. The patient's chart or medical record may be used as the test requisition or authorization.

If a specimen aliquot is sent to another laboratory for additional testing (eg, reflex testing from primary HPV screening), all required requisition elements must accompany the specimen.

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):7162 [42CFR493.1241(c)]
2) Valenstein P, Howanitz PJ. Ordering accuracy: a College of American Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med.* 1995;119:117-122
3) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150

GEN.41042 Refrigerator/Freezer Temperatures — Phase II

The laboratory monitors and records refrigerator/freezer temperatures using a calibrated thermometer daily, as defined in written procedure.

NOTE: This checklist requirement applies to refrigerators/freezers containing reagents or patient/client specimens. "Daily" means every day (7 days per week, 52 weeks per year). The laboratory must define the acceptable temperature ranges for these units. If temperature(s) are found to be outside of the acceptable range, the laboratory must record appropriate corrective action, which may include evaluation of contents for adverse effects.

Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording the temperature(s) must be recorded (the initials of the individual are adequate).

If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the automated system, in accordance with manufacturer's instructions. This does not require routine daily review of the system records.

Use of a continuous monitoring device or a minimum/maximum thermometer satisfies the requirement for daily temperature recording, including during laboratory closures (eg, weekends, holidays), as long as the monitoring data is evaluated on the next business day prior to use. For use of minimum/maximum thermometers during laboratory closures, this includes resetting the device prior to the monitoring period and recording both the low and high temperatures. when the laboratory reopens. It is not necessary to record low and high temperatures on days when the

laboratory is in operation if daily temperatures are recorded. ~~*This does not require routine daily review of the system records.*~~

Patient specimens, reagents, and controls may be stored in a frost-free freezer only if protected from thawing. Thermal containers within the freezer may be used. The laboratory must retain records showing that the temperatures stay within the defined range.

- *Repeated freeze-thaw cycles contribute to biomolecular degradation and are detrimental to biospecimen quality.*
- *It is prudent to avoid freeze-thaw altogether by aliquoting specimens before freezing.*

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(b)(2)]

RESULTS REPORTING AND REFERRAL OF TESTING

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

GEN.41096 Report Elements **Phase II**

The paper or electronic report includes the following elements~~.~~:

1. **Name and address of testing laboratory (see note below)**
2. **Patient name and identification number, or unique patient identifier and identification number**
3. **Name of physician of record, or legally authorized person ordering test, as appropriate**
4. **Name of the test(s) performed**
5. **Date of specimen collection, and if appropriate, time of collection**
6. **Date of release of report (if not on the report, this information should be readily accessible)**
7. **Time of release of report, if applicable (if not on the report, this information should be readily accessible)**
8. **Specimen source, when applicable**
9. **Test result(s) and units of measurement, when applicable**
10. **Reference intervals, as applicable**
11. **Conditions of specimen that may limit adequacy of testing**

NOTE: All of the above data elements, as applicable, must be available in the laboratory information system or in paper records, and must be in the report that is available/sent to the clinician, whether electronic or paper, including electronic reports in systems interfaced to the laboratory information system directly or through middleware or an interface engine. For electronic reports, data elements need not all be present on one screen, but must be readily available.

If digitized images or data are reviewed and interpreted by laboratory personnel on a recurrent or regular basis at a remote site under the laboratory's CAP/CLIA certificate, reports must indicate the remote site location using the address or a coding system to designate the site (eg, private residence). All the required data in the report, as listed above, must be present in reports issued from a remote site location. If review and interpretation occur at a site with a separate CAP/CLIA certificate, it is considered under the purview of the separate laboratory. Remote review of physical slides is not allowed by the Center for Medicare and Medicaid Services. More stringent national, federal, state (or provincial), and local regulations relating to remote sites must be followed.

The paper or electronic report must include the name and address of referral laboratories where patient testing was performed. For laboratories subject to US regulations, a "referral laboratory" includes outside referral laboratories as well as any affiliated or special function laboratory that is separately accredited and has a different CLIA registration number than the referring laboratory.

For electronic reports, the name and address of referral laboratories need not all be present on the same screen(s) as the results but must be available to the clinician in the information system.

The laboratory must report reference intervals or interpretations with patient/client results, where such exist, to allow for proper interpretation of patient/client data. Age- and/or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions which are based on the test result (eg, activated clotting time in cardiac surgery).

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals ~~to all~~(printed copies or electronic data) to users and sites where reports are received. ~~This system~~The laboratory must ensure that such data is ~~acceptable if rigidly controlled~~up to date.

Patient reports must state the name of the physician (or other legally authorized person) ordering the test(s) or a physician of record. In those institutions where there are multiple ordering physicians and/or frequent changing of attending physicians, the ordering physician should be easily identifiable through a computer audit trail or other records of the test order.

Referral laboratories accredited by the CAP must provide a copy of the results to the referring laboratory (~~Exceptions~~exceptions to this requirement may be made under special circumstances or for special categories of testing, such as drugs of abuse or employee drug testing. The laboratory director may make these exceptions.). Results may be reported to the ordering physician of record (or other legally authorized person) by either the referral laboratory or the referring laboratory.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):3713 [42CFR493.1291~~(c)~~].
2) Tietz NW, ed. Clinical guide to laboratory tests. Philadelphia: WB Saunders, 1990
3) Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline-Third Edition.* CLSI Document EP28-A3c. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.
4) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.~~1291(h)(i)(3)] and [42CFR493.~~1283(a)(1)]

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

GEN.41316 **Significant Infectious Disease ~~Reporting~~Diagnoses** **Phase II**

The laboratory ~~communicates~~ensures communication of diagnoses of infectious diseases of particular significance ~~(eg, human immunodeficiency virus and tuberculosis) in a timely manner, and retains records of the communication.~~ to the physician or other clinical personnel responsible for patient care and records of those communications are retained.

~~*NOTE: The laboratory must have a policy to ensure that diagnoses of human immunodeficiency virus infection and other serious infections (for example, tuberculosis) are communicated to the responsible clinician in a timely manner.*~~

NOTE: Certain infectious disease diagnoses may be considered significant and warrant special communication to the responsible physician or other clinical personnel responsible for patient care. The laboratory, ideally in consultation with medical staff and infection control, must determine which infectious diseases (eg, HIV, tuberculosis) are considered "particularly significant". Considerations include isolation procedures or contact precautions that may be initiated based on a specific diagnosis.

An appropriate notification includes a direct dialog with the responsible individual or an electronic communication (secure email or fax) with confirmation of receipt by the responsible individual. The record of the communication may be included directly on the patient report or in a separate location.

Referral laboratories may report these results directly to clinical personnel, or to the referring laboratory. The referral laboratory must have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports infectious disease results of particular significance.

When a distributive workflow is used, such as for next generation sequencing where different laboratories may perform different components of the testing process (eg, nucleic acid extraction, wet bench testing, bioinformatics, and interpretation), the role of each laboratory in significant finding reporting is clearly delineated to allow for timely reporting of significant findings and take additional actions as needed.

The intent of this checklist item is NOT to require that these diagnoses be treated as critical results (this decision is up to the laboratory director); rather, the intent is that the laboratory assures that its reporting system is effective.

Evidence of Compliance:
✓ List of infectious diseases requiring notification to the clinician **AND**
✓ Records of communication for the specified infectious diseases

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

GEN.41318 Reporting and Submission of Materials to Public Health Authorities Phase II

The laboratory ensures there is a mechanism in place to report test results and submit materials (specimens and/or culture isolates) to public health authorities, if required by national, federal, state (or provincial), and local laws and regulations.

NOTE: The laboratory must ensure that it is following current laws and regulations. The CAP recommends that the laboratory retain a current copy of applicable regulations and conduct an annual review, as these requirements are subject to change in response to current conditions.

Evidence of Compliance:
✓ Records of reporting and submission of required materials to public health authorities **OR**
✓ Defined reporting mechanism

PERSONNEL

SECTION DIRECTORS (TECHNICAL SUPERVISORS)/GENERAL SUPERVISORS

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

GEN.53400 Section Director ~~(~~/Technical Supervisor~~)~~ Qualifications/Responsibilities Phase II

Section ~~Directors/Technical Supervisors~~directors/technical supervisors of high complexity testing meet defined qualifications for the specialties supervised and fulfill the expected responsibilities.

NOTE 1: For high complexity testing, one or more individuals qualified as a technical supervisor must be identified on the CAP's Laboratory Personnel Evaluation Roster.

Requirements for the section directors of clinical cytogenetics, histocompatibility, molecular pathology, and transfusion medicine services are more stringent and are found in the Cytogenetics, Histocompatibility, Molecular Pathology, and Transfusion Medicine Checklists, respectively.

The technical supervisor must meet the following requirements:

1. *MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with certification in anatomic pathology or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology ~~or possess qualifications equivalent to those required for certification~~.*
   - *If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology ~~or possess equivalent qualifications~~*
   - *If responsible for clinical pathology must be board certified in clinical pathology ~~or possess equivalent qualifications~~*
   - *If responsible for anatomic pathology and/or cytopathology, and clinical pathology, must be board certified in both anatomic and clinical pathology ~~or possess equivalent qualifications~~ **~~OR~~***

OR:

2. *For specialties other than ~~Anatomic Pathology~~anatomic pathology and ~~Cytopathology~~cytopathology, an individual will meet the qualifications of a technical supervisor providing the following qualifications are met:*
   - *MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with at least one year of training and/or experience in high-complexity testing*; or*
   - *Doctoral degree in chemical, ~~physical,~~ biological ~~or~~, clinical or medical laboratory science, or medical technology from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*; or*
   - *Master's degree in a chemical, ~~physical,~~ biological, ~~or~~ clinical or medical laboratory science, or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or*
   - *Bachelor's degree in a chemical, ~~physical, or~~ biological, or clinical or medical laboratory science, or medical technology from an accredited institution with at least four years of laboratory training and/or experience in high complexity testing*.*

**The technical supervisor's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible and relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition.*

*For ~~**laboratories subject**~~microbiology, there must also be a minimum of six months of experience in high complexity testing in the applicable subspecialties.*

*Individuals qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, may continue to ~~**US regulations, alternate**~~fill this role if they have done so continuously since December 28, 2024.*

*More detailed information on technical supervisor qualifications ~~**for the following**~~, including specialty ~~**areas**~~and discipline-specific requirements and additional educational pathways for individuals with doctoral, master's, and bachelor's degrees, can be found in ~~**Fed Register. 1992 (Feb 28): 7177-7180 [**~~the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists and in CLIA regulation 42CFR493.1449~~**]: bacteriology, mycobacteriology, mycology, parasitology, virology, cytology, ophthalmic pathology, dermatopathology, oral pathology, and radiobioassay~~.*

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

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. 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.

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.

NOTE 2: The section director, as designated by the laboratory director, must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for the technical and scientific oversight of the laboratory. The section director is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualifications for high complexity testing. Other responsibilities of the technical supervisor include:

- *Selection of test methodology*
- *Establishment or verification of laboratory test performance specifications*
- *Enrollment and participation in proficiency testing*
- *Establishment of a quality control program to monitor ongoing test performance*
- *Resolution of technical problems and ensuring that remedial actions are taken*
- *Ensuring that patient/client results are not reported until corrective actions are taken and test systems are functioning properly*
- *Identification of training needs*

For functions that are delegated, such as review of quality control data, assessment of competency, or review of proficiency testing performance, delegation must be in writing and the technical supervisor is responsible to ensure that those functions are properly carried out by a qualified individual.

Evidence of Compliance:

✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required) **AND**
✓ Certification/registration (if required) and work history in related field **AND**
✓ Description of current duties and responsibilities **AND**
✓ Record of delegation of duties

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~~):7180~~]:[42CFR493.1451] and [42CFR493.1449].

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

GEN.53600 General Supervisor Qualifications/Responsibilities Phase II

Supervisors/general supervisors meet defined qualifications and fulfill expected responsibilities.

NOTE: For high complexity testing, one or more individuals qualified as a general supervisor must be defined on the CAP's Laboratory Personnel Evaluation Roster.

Supervisors who do not qualify as a laboratory director or section director/technical supervisor must qualify as testing personnel and ~~possess the~~have a minimum of ~~a~~one of the following:

1. *Bachelor's degree in a chemical, ~~physical,~~ biological ~~or~~, clinical or medical laboratory science, or medical technology with at least one year of training and/or experience in high complexity testing*; or*
2. *Associate degree in a laboratory science or medical technology or equivalent education and training as defined in 42CFR493.1489(b)(~~2~~3)(ii), with at least two years of training and/or experience in high complexity testing*; or*
3. ~~Have previously qualified or could have qualified~~*Qualified and served as a general supervisor ~~prior to February~~in a CLIA-certified laboratory as of December 28, ~~1992~~2024, and have done so continuously since December 28, 2024.*

**The general supervisor's training and experience must be in the designated discipline or area of service for which the individual is responsible and relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition.*

Requirements for the ~~supervisors/~~general supervisors of cytopathology, cytogenetics, histocompatibility, and molecular pathology are more stringent and are found in the Cytopathology, Cytogenetics, Histocompatibility, and Molecular Pathology Checklists.

Additional information on personnel qualifications, such as qualifications for blood gas supervisors, can 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.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure (eg, California), they must be followed.

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. 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.

The supervisor of high-complexity testing must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Individuals meeting the qualifications of a general supervisor for high complexity testing may assess ~~the~~semiannual and annual competency ~~of~~in laboratories performing both moderate and high complexity testing ~~personnel~~, if this duty is delegated, in writing, by the section director. Other responsibilities of the general supervisor include:

- *Resolution of technical problems in accordance with policies and procedures established by the laboratory director or technical supervisor*
- *Monitoring of test performance*
- *Ensuring that remedial actions are taken when test systems deviate from the laboratory's established performance specifications*
- *Providing orientation of testing personnel*

Evidence of Compliance:

✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current laboratory personnel license (if required) **AND**
✓ Certification/registration (if required) and work history in related field **AND**
✓ Description of current duties and responsibilities

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~~):7182~~):[42CFR493.1461] and [42CFR493.1463~~]~~].

TECHNICAL AND CLINICAL CONSULTANT

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

GEN.53625 Technical Consultant Qualifications/Responsibilities Phase II

Technical consultants meet defined qualifications and fulfill expected responsibilities.

NOTE: This requirement applies to all laboratories that are performing any moderate complexity testing. It is not applicable if the laboratory only performs high complexity testing. For moderate

complexity testing, one or more individuals qualified as a technical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster.

The technical consultant (including the laboratory director who serves as a technical consultant) must be qualified by education and experience by one of the following combinations:

- *MD or DO, licensed to practice medicine in the jurisdiction where the laboratory is located (if required), with certification in anatomic and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology~~, or possess qualifications equivalent to those required for certification~~; or*
- *MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), with at least one year of training and/or experience in nonwaived testing*; or*
- *Doctoral or master's degree in a chemical, ~~physical,~~ biological, ~~or~~ clinical or medical laboratory science, or medical technology from an accredited institution with at least one year of training and/or experience in nonwaived testing*; or*
- *Bachelor's degree in a chemical, ~~physical,~~ biological, clinical or medical laboratory science, or medical technology from an accredited institution, with at least two years of training and/or experience in nonwaived testing~~*~~*; or*
- *Associate's degree in medical laboratory technology, medical laboratory science, or clinical laboratory science with at least four years of training and/or experience in nonwaived testing*; or*
- *Qualified and served as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.*
- *For moderate complexity blood gas testing only, qualify with a bachelor's degree or higher as listed above, **OR** have an earned bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution and have at least two years of education and/or experience in blood gas analysis.*

**The technical consultant's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible and relate to testing of human specimens for the purpose of diagnosing, treating, and monitoring an individual's condition.*

Additional educational pathways for qualifying as a technical consultant 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.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure (eg, California), they must be followed.

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. 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.

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.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant must be available to the laboratory as needed for telephone, electronic and on-site consultation. Individuals meeting the qualifications of a technical consultant may assess the semiannual and annual competency of personnel performing moderate complexity testing~~,~~ if this duty is delegated, in writing, by the laboratory director. Other responsibilities of the technical consultant include:

- *Establishment or verification of laboratory test performance specifications*
- *Selection of test methodology*

- *Enrollment and participation in proficiency testing*
- *Establishment of a quality control program to monitor ongoing test performance*
- *Resolution of technical problems and ensuring that remedial actions are taken*
- *Ensuring that patient results are not reported until corrective actions are taken and test systems are functioning properly*
- *Identification of training needs*

Evidence of Compliance:

✓ Records of technical qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required) **AND**
✓ Certification/registration (if required) and work history in related field **AND**
✓ Description of current duties and responsibilities

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):101053 [42CFR493.1411] and~~ 2003(Oct 1~~) 1053-54 [~~):[42CFR493.1413]
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):[42CFR493.1411].

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

GEN.53650 Clinical Consultant Qualifications/Responsibilities **Phase II**

Clinical consultants meet defined qualifications and fulfill expected responsibilities.

NOTE: This requirement applies to laboratories performing moderate complexity testing and/or high complexity testing. One or more individuals qualified as a clinical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster.

Clinical consultants must be ~~an~~:

- *An MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required~~) or doctoral scientist certified by an HHS-approved board.~~); **or***
- *A doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution, certified by an HHS-approved board with at least 20 CE credit hours in laboratory practice that cover the director responsibilities, **and***
  - *For **high complexity testing**, at least two years of laboratory training or experience, or both, and experience supervising high complexity testing; **or***
  - *For **moderate complexity testing**, at least one year of experience directing or supervising nonwaived laboratory testing.*

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.

Detailed information on clinical consultant qualifications is provided in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

If more stringent state or local regulations are in place for clinical consultant qualifications, including requirements for state licensure (eg, California), they must be followed.

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. 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.

The clinical consultant must be available to provide and ensure that consultation is available on test ordering, and interpretation of results relating to specific patient conditions, and for matters relating to the quality of test results reported. The clinical consultant must also ensure that patient/client reports include pertinent information required for interpretation. See DRA.10440, DRA.10500, and DRA.10700.

Evidence of Compliance:

✓ Records of clinical consultant qualifications (ie, a valid medical license **AND**
✓ Written job description or contract **AND**
✓ Records of activities performed by the consultant during visits consistent with the job description (eg, meeting minutes, activity logs, signed summaries or data with evidence of review)

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1415], [42CFR493.1417~~9~~], [42CFR493.~~1419]~~ 1453], [42CFR493.1457].
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28): [42CFR493.1417] and [42CFR493.1455].

ALL PERSONNEL

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

GEN.54025 Laboratory Personnel Evaluation Roster **Phase II**

The Laboratory Personnel Evaluation Roster is current and accurate and is audited by the laboratory director or designee at least annually for nonwaived testing personnel and personnel fulfilling supervisor roles.

NOTE: The laboratory's audit of the laboratory personnel evaluation roster must include a review of a mixture of the following types of personnel:

- ***All** nonwaived testing personnel hired within the last 12 months (laboratory and non-laboratory)*
- *Laboratory and non-laboratory (POC, PPT, Radiology, Respiratory, etc.) personnel*
- *Full and part-time nonwaived testing personnel on all shifts and throughout all departments*
- *Personnel fulfilling supervisory roles (eg, laboratory director, technical supervisor, staff pathologist)*

Personnel performing any CLIA-defined duty must be listed on the roster. Personnel performing waived testing only or whose duties are limited to phlebotomy, clerical work, or specimen processing are not required to be listed on the Laboratory Personnel Evaluation Roster. Histology personnel that do not perform high complexity testing are also excluded. All grossing performed in histology is considered high complexity testing.

Personnel that perform remote review and interpretation of digitized images and data under the laboratory's CAP/CLIA certificate must be listed on the Laboratory Personnel Evaluation Roster. A list of personnel working remotely must be available upon request.

Evidence of Compliance:

✓ Records of completed rosters accurately reflecting personnel **AND**
✓ Records of annual audits performed by the laboratory director or designee

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

GEN.54750 Nonwaived Testing Personnel Qualifications **Phase II**

All nonwaived testing personnel meet the following requirements~~.~~:

1. **Personnel performing high complexity testing must have a minimum of one of the following:**
   - **Bachelor's degree in a chemical, ~~physical,~~ biological ~~or~~, clinical or medical laboratory science or medical technology from an accredited institution; or**
   - **Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution, or ~~equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489 (see NOTE 2); or~~**
   - **~~Meet other provisions~~Equivalent laboratory training and experience meeting the requirements defined in CLIA regulation 42CFR493.1489(b)(3)(ii) (see NOTE 2~~)(B)(4)~~); or ~~42CFR493.1489(b)(2)(B)(5)(i) for personnel performing~~**
   - **Successful completion of at least a 50 week official US military medical laboratory procedures training course and currently hold or have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or**
   - **Qualified and served as high complexity testing ~~on or before April 24, 1995 (refer to the CLIA regulations for more details)~~personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.**
2. **Personnel performing moderate complexity testing, including non-laboratory personnel, must qualify as high complexity testing personnel or have a minimum of one of the following:**
   - **Associate degree in a chemical, ~~physical, or~~ biological~~,~~ clinical or medical laboratory science ~~or~~, medical laboratory technology, or nursing from an accredited institution; or**
   - **High school graduate or equivalent and ~~have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist~~meet the requirements defined in NOTE 4; or**
   - **High school ~~diploma~~graduate or equivalent and ~~have a record~~completion of an official US military medical laboratory procedures training ~~defined in~~ course of at least 50 week duration and currently hold or have held the ~~CLIA regulation 42CFR493.1423 (see NOTE 4)~~ military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).**
   - **For blood gas testing only, meet the qualifications above or have:**
     - **1) a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution with at least one year of laboratory training or experience, or both, in blood gas analysis; OR 2) an associate's degree related to pulmonary function from an accredited institution with at least two years of laboratory training or experience, or both, in blood gas analysis**

NOTE 1: Detailed information on testing personnel qualifications, including high complexity testing qualifications prior to December 28, 2024, are provided in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

Laboratory and non-laboratory (eg, nurses, respiratory therapists, radiologic technologists, and medical assistants) testing personnel must meet the qualifications appropriate to the complexity of testing performed. GEN.54400 contains the specific requirements for the types of records that must be retained in the personnel file to demonstrate compliance. ~~A more detailed listing of personnel qualifications can be found in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources.~~

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

NOTE: 2: For high complexity testing, equivalent laboratory training and experience includes the following:

- *60 semester hours or equivalent from an accredited institution that, at a minimum, includes either 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination; AND*
- *Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ~~ABHES, NAACLS, or other organization approved by HHS~~Accrediting Bureau of Health Education Schools (ABHES) or the Commission on Accreditation of Allied Health Education Programs (CAAHEP) (note that this training may be included in the 60 semester hours listed above), OR at least three months documented laboratory training in each specialty in which the individual performs high complexity testing.*

NOTE 3: For US Department of Defense laboratories, effective May 29, 2014, newly hired high complexity testing personnel must have either:

- *A minimum of an associate degree in a biological or chemical science or medical laboratory technology from an accredited institution **AND** be certified by the ASCP, AMT or other organization deemed comparable by OASD(HA) or their designee Center for Laboratory Medicine Services (CLMS) as an MLT or MT/MLS; OR*
- *Successfully completed an official ~~U.S.~~US military medical laboratory procedures training course of at least 50 weeks duration and currently hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).*

NOTE 4: For moderate complexity testing personnel qualifying with a high school diploma or equivalent qualifications only, training records must demonstrate skills for the following:

- *Specimen collection, including patient preparation, labeling, handling, preservation, processing, transportation, and storage of specimens, as applicable;*
- *Implementation of all laboratory procedures;*
- *Performance of each test method and for proper instrument use;*
- *Preventive maintenance, troubleshooting and calibration procedures for each test performed;*
- *Working knowledge of reagent stability and storage;*
- *Implementation of quality control policies and procedures;*
- *An awareness of interferences and other factors that influence test results; and*
- *Assessment and verification of the validity of test results, including the performance of quality control prior to reporting results.*

NOTE 5: Students gaining experience in the field must work under the direct supervision of a qualified individual.

NOTE 6: ~~If more stringent state or local regulations are~~Laboratories in ~~place for personnel~~the CAP's Forensic Drug Testing (FDT) accreditation program must meet qualifications~~, including requirements for state licensure, they must be followed~~ equivalent to those described for the complexity of testing performed.

Evidence of Compliance:

✓ Records of qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required) **AND**
✓ Work history in related field

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.~~1423], 7183~~.]. [42CFR493.1489~~]~~].
2) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment.* 4th ed. CLSI guideline QMS03. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

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GEN.55499 Competency Assessment - Waived Testing **Phase II**

The competency of personnel performing waived testing is assessed for each test system at the required frequency.

NOTE: Competency assessment evaluates an individual's ongoing ability to apply knowledge and skills to achieve intended results.

Competency must be assessed at the following frequency:

- *After an individual has performed assigned duties for one year, and at least annually thereafter. This can be performed throughout the entire year to minimize impact on workload.*
- *When problems are identified with an individual's performance.*

*If more stringent state and local regulations are in place for competency assessment of waived testing (eg, California), they must be followed. ~~Laboratories with~~ California regulation CCR Title 17 1036.3 states that a waived laboratory ~~**licensure** must assess~~supervisor is responsible for evaluating and documenting competency at least semiannually during the first year an individual tests patient specimens and annually thereafter.*

The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures. Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. The laboratory director may determine how competency will be assessed for personnel performing waived testing at multiple test sites (same CAP/CLIA number) or laboratories within the healthcare system (different CAP/CLIA numbers). If there are variations on how a test is performed at different test sites or laboratories, those variations must be included in the competency assessment specific to the site or laboratory.

*For waived test systems, the laboratory may select which elements to assess. It is not necessary to assess all six elements listed below at each assessment event unless more stringent state and local regulation are in place (eg, California~~, where each assessment **must include**~~ regulation CCR Title 17 1036.3, which includes elements 1, 2, 3, 4, and 6, below). Elements of competency assessment include, but are not limited to:*

1. *Direct observations of routine test performance, including, as applicable, patient/sample identification and preparation; and specimen collection, handling, processing and testing*
2. *Monitoring the recording and reporting of test results, including, as applicable, reporting critical results*
3. *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records*
4. *Direct observation of performance of instrument maintenance and function checks, as applicable*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens) or external proficiency testing specimens; and*
6. *Evaluation of problem-solving skills.*

Evidence of Compliance:

✓ Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required frequency

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):101053 [42CFR493.1411] and~~ 2003(Oct 1~~) 1053-54 [~~):[42CFR493.1413~~]~~.
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):[42CFR493.1411].
~~2~~3) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med.* 2000;124:190-191

~~3~~4) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202
~~4~~5) Kost GJ. Preventing medical errors in point-of-care testing. *Arch Pathol Lab Med*. 2001;125:1307-1315.
~~5~~6) Deobald GR, et al. Two approaches to competency assessment for point of care testing. *Clin Chem.* 2001;47(suppl):A187.
~~6~~7) California Code of Regulations, Title 17 §1036.3.

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GEN.55510 Competency Assessment - Assessor Qualifications **Phase II**

Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed.

NOTE: The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the assessor vary by the complexity of the testing. The assessor must be knowledgeable about the test systems but is not required to have completed a competency assessment for those test systems unless the assessor is also defined as testing personnel for that test system.

For laboratories subject to US regulations, the following include the minimum qualifications for assessors:

- *High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications (GEN.53400, GEN.53600)*
- *Moderate complexity testing: Technical consultant or individual meeting those qualifications (GEN.53625~~)~~)**
- *Waived testing: May be determined by the laboratory director.*

*~~For~~*If both* moderate *and high* complexity testing~~, the individual assessing competency must have a minimum of a bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology, with at least two years of training and/or experience in nonwaived testing in the designated specialty or subspecialty area of service for which the individual~~ *is ~~responsible. This includes~~performed, a general supervisor or individual meeting those qualifications may assess the competency for both* moderate *and high* complexity testing ~~performed within the main laboratory, as well as~~ .*

Competency of moderate complexity ~~testing performed in blood gas laboratories and~~ point-of-care ~~testing locations~~*and blood gas testing personnel must be assessed by an individual meeting technical consultant qualifications.*

Additional information on the qualifications for assessing competency, including additional qualifications for blood gas supervisory personnel, may be found in the requirements listed above and in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure (eg, California), they must be followed.

~~For~~For waived testing performed at laboratories with California laboratory licensure, ~~competency of waived testing personnel must be assessed by an individual meeting~~California regulation CCR 17 1036.3 states that a waived laboratory supervisor ~~qualifications~~ is responsible for evaluating and documenting competency (refer to GEN.78250).

For laboratories not subject to US regulations, individuals assessing competency must, at minimum, meet the personnel qualifications to perform the test and be knowledgeable on the testing performed.

Evidence of Compliance:

✓ Records of competency assessments performed by qualified individuals **AND**
✓ Records of assessor qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, or current license (if required)

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(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413~~], 1992 (Feb 28) 7184 [42CFR493.1713]~~.]
2) Department of Health and Human Services, Centers for Medicare ~~and~~& Medicaid Services. ~~Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/clia_compbrochure_508.pdf~~Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Dec 28):[42CFR493.1451(b)] and [42CFR493.1463(b)].
3) California Code of Regulations, Title 17 §1036.3.

LABORATORY SAFETY
FIRE PREVENTION AND PROTECTION

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

GEN.75300 Fire Exit **Phase II**

Each room larger than 1000 ft² (92.9 m²), or in which major fire hazards exist, has at least two exit access doors remote from each other, one of which opens directly into an exit route.

NOTE: The local fire authority is ultimately responsible for fire protection and prevention. Any site-specific arrangements that vary from what is defined in this requirement must be approved by that authority.

Evidence of Compliance:

✓ Records of any site-specific arrangements approved by the local fire authority, when necessary

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2019 edition

ENVIRONMENTAL SAFETY

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GEN.77400 Emergency Eyewash **Phase II**

The laboratory has adequate plumbed or self-contained emergency eyewash facilities safely placed in every area where exposure to the eye from corrosive chemicals, as defined by the laboratory's chemical hygiene plan, may occur. Testing records are retained.

NOTE: The chemical hygiene plan must include provisions for the safe handling of all chemicals used in the laboratory. Chemicals with corrosive properties (refer to the safety data sheet) that may potentially be exposed to the eye must be handled in a work area with appropriate eyewash facilities. A risk-based approach may be used to determine appropriate eyewash facility placement (eg, in the vicinity of the hazard, but positioned so as not to pose a risk of splash of hazardous liquids or other hazard to the user). It is recommended that plumbed eyewash facilities be located at a sink not used for preparation or disposal of chemicals/stains/reagents/body fluids. It is the responsibility of the inspector to determine if the eyewash location is acceptable.

For plumbed eyewash stations as well as self-contained eyewash ~~facilities such as stand-alone eyewash~~ units containing flushing fluid, ~~the~~ manufacturer's ~~specifications~~instructions must be followed for maintenance, which may include flushing deposits, testing for functionality, and/or

microbial contamination, where applicable. These records must be available for review by an inspector.

Disposable eyewash bottles or other personal wash devices, such as single head drench hoses:

- *Cannot replace the need for plumbed or self-contained emergency eyewash units in areas at risk for eye exposure from corrosive chemicals*
- *Can be used to supplement plumbed or self-contained emergency eyewash equipment*
- *May be kept in the immediate vicinity of employees working in a potentially hazardous work area but located away from bottles containing chemicals to avoid confusion in an emergency.*

Immediate and prolonged (15 minutes) flushing is generally necessary for corrosive/alkali agents and cannot be done using disposable eyewash bottles or other personal wash devices. If the water is not at an appropriate temperature, it may add to the injury.

The eyewash facilities must meet the following criteria:

For all laboratories:

1. *No greater than 10 seconds (approximately 55 feet or 16.8 meters) travel distance from areas in the laboratory where hazardous chemicals are present*
2. *Visible and well-lit signage for location of eyewash*
3. *Unobstructed path with unlocked doors opening in the direction of the eyewash*
4. *Tepid fluid temperature (Water temperature should be between 16°C and 38°C (60°F and 100°F). ~~Actual temperature recording~~This is not required~~.)~~ to be recorded.*
5. *Plumbed systems are activated weekly to verify operation and ensure flushing fluid is available*
6. *Self-contained units are visually examined weekly to determine if flushing needs to be supplemented or changed.*

In addition, the following are required for laboratories subject to US OSHA regulation and are recommended for all laboratories:

7. *Capable of delivering 1.5 L per minute for 15 minutes*
8. *Flow is provided to both eyes simultaneously*
9. *Nozzles or covers to protect from airborne contaminants*
10. *Hands-free flow once activated*
11. *Plumbed systems are protected from unauthorized shut off*

Evidence of Compliance:

✓ Records of weekly activation (for plumbed systems) or weekly visual examination (for self-contained units) **AND**

✓ Maintenance records

REFERENCES

1) American National Standards Institute. Emergency eyewash and shower equipment. New York, NY: ANSI, Z358.1-2014.
2) Occupational Safety and Health Administration. Medical and first aid. Medical services and first aid. US Government Printing Office, 2011(December 27):[29CFR1910.151(c)]
3) OSHA Infosheet: Health Effects from Contaminated Water in Eyewash Stations. Occupational Safety and Health Administration Website. https://osha.gov/sites/default/files/publications/OSHA3818.pdf. Reviewed July 2015. Accessed July 6, 2023.
4) Swanson CS, Williams JM, He Q. Risks of exposure to microbial contamination in eyewash stations. *Am J Infect Control*. 2023;51(7):838-840.