COLLEGE of AMERICAN PATHOLOGISTS

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Laboratory Department

Laboratory General Checklist

CAP Accreditation Program

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Laboratory General Checklist

TABLE OF CONTENTS

SUMMARY OF CHANGES....4
UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS....6
INTRODUCTION....6
DEFINITION OF TERMS....7
QUALITY MANAGEMENT SYSTEM....12
SPECIMEN COLLECTION, HANDLING, AND REPORTING....23
SPECIMEN COLLECTION INSTRUCTIONS....23
SPECIMEN COLLECTION AND LABELING....26
SPECIMEN TRANSPORT AND TRACKING....28
BLOOD CULTURE SPECIMEN COLLECTION FOR REFERRAL ONLY....30
REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/PROCESSING....31
RESULTS REPORTING AND REFERRAL OF TESTING....34
QUALITY OF WATER AND GLASSWARE WASHING....41
LABORATORY COMPUTER SERVICES....42
COMPUTER FACILITY....42
HARDWARE AND SOFTWARE....43
SYSTEM SECURITY....44
PATIENT/CLIENT DATA....45
DATA RETRIEVAL AND PRESERVATION....46
INTERFACES....47
PERSONNEL....48
SECTION DIRECTORS (TECHNICAL SUPERVISORS)/GENERAL SUPERVISORS....48
TECHNICAL AND CLINICAL CONSULTANT....51
ALL PERSONNEL....54
PHYSICAL FACILITIES....62
SPACE....62
ENVIRONMENT....63
COMMUNICATIONS....64
INVENTORY AND STORAGE OF SUPPLIES....64
POWER....65
LABORATORY SAFETY....66
SAFETY POLICIES, PROCEDURES, AND RECORDS....66
INFECTION PREVENTION AND CONTROL....68
FIRE PREVENTION AND PROTECTION....71
ELECTRICAL SAFETY....73
CHEMICAL SAFETY....74
COMPRESSED GASES....77
RADIATION SAFETY....78
ENVIRONMENTAL SAFETY....78
OTHER HAZARDS....80
WASTE DISPOSAL....81

ON-LINE CHECKLIST DOWNLOAD OPTIONS

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

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

CHECKLIST ACCREDITATION RESOURCES

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

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

SUMMARY OF CHECKLIST EDITION CHANGES
Laboratory General Checklist
12/26/2024 Edition

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

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

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

Previously Cited Checklist Requirements

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

NEW Checklist Requirements

Requirement	Effective Date
GEN.41318	12/26/2024
GEN.76710	08/24/2023

REVISED Checklist Requirements

Requirement	Effective Date
GEN.13806	12/26/2024
GEN.20335	12/26/2024
GEN.20351	08/24/2023
GEN.20377	08/24/2023
GEN.26791	12/26/2024
GEN.30000	12/26/2024
GEN.40032	08/24/2023
GEN.40560	12/26/2024
GEN.40750	12/26/2024
GEN.41096	12/26/2024
GEN.41316	12/26/2024
GEN.41770	08/24/2023
GEN.43022	08/24/2023
GEN.43450	08/24/2023
GEN.53400	12/26/2024
GEN.53600	12/26/2024
GEN.53625	12/26/2024
GEN.53650	12/26/2024
GEN.54025	12/26/2024
GEN.54750	12/26/2024
GEN.55499	12/26/2024
GEN.55510	12/26/2024
GEN.61300	08/24/2023
GEN.73200	08/24/2023
GEN.75200	08/24/2023
GEN.75300	12/26/2024
GEN.76400	08/24/2023
GEN.77400	12/26/2024
GEN.77600	08/24/2023

DELETED/MOVED/MERGED Checklist Requirements

Requirement	Effective Date
GEN.40700	08/23/2023
GEN.41497	08/23/2023

UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

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

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

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

INTRODUCTION

The 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 a relationship between two or more measured values.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Semiannual - Every 6 calendar months.

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

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

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

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

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

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

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

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

QUALITY MANAGEMENT SYSTEM

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

This section of the checklist assesses quality management throughout a laboratory's operation.

There are additional QMS related requirements in other checklists that pertain to specific types of testing. The All Common Checklist includes requirements for integrating the QMS into each laboratory section. The Director Assessment Checklist includes requirements for effective organization and oversight.

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

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

GEN.13820 Scope of Service **Phase I**

There is a document that describes the patient care and client services offered by the laboratory (eg, tests offered, hours of operation, turnaround times).

NOTE: The laboratory's scope of service document (paper or electronic) must be available to the clinicians/patients it serves. The laboratory's user manual (eg, test directory/laboratory service guide) and/or specimen collection manual may meet the intent of this requirement.

The scope of service document does not include financial or business arrangements between the pathology group and the institution.

GEN.20100 QMS Extent of Coverage **Phase II**

The QMS covers all areas of the laboratory and all beneficiaries of service (eg, clinical staff, patients and/or clients).

NOTE: The QMS must be implemented in all areas of the laboratory (eg, chemistry, anatomic pathology, satellite, point-of-care, consultative services). The QMS must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and referral laboratory services.

GEN.20208 Identification of Non-conforming Events **Phase II**

The QMS includes a process to identify and record non-conforming events.

NOTE: Non-conforming events include problems such as errors and incidents that may interfere with patient care/client services (refer to the Definition of Terms).

There must be a process for recording problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on

all shifts. Any problem that could potentially interfere with patient care/client services or safety must be addressed.

Clinical, rather than business/financial issues, must be emphasized.

GEN.20310 Investigation of Non-conforming Events **Phase II**

The QMS requires a root cause analysis (RCA) when a non-conforming event occurs that results in death, permanent harm or severe temporary harm (eg, sentinel event). For non-conforming events that represent a risk to patients, donors, employees, or the health and safety of the general public, but are not sentinel events (eg, near misses), the QMS includes a process to define the scope and extent of the investigation required.

NOTE: An RCA is a systematic process for identifying the causal factor(s) that underlie errors or potential errors in care. By conducting an RCA and addressing root causes, the laboratory may be able to substantially reduce or completely eliminate the same or a similar incident from recurring. Laboratories must demonstrate appropriate risk-reduction activities based on such investigations, as applicable.

Methods used to perform RCAs may vary. Helpful tools on RCA can be found on cap.org behind e-Lab Solutions Suite under Accreditation Resources-Quality Management.

Evidence of Compliance:

- ✓ Records of non-conforming event investigations (including those requiring root cause analysis)

GEN.20316 QMS Indicators of Quality **Phase II**

The QMS includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases by regularly comparing performance against targets defined by the laboratory.

NOTE: Key indicators must monitor activities integral to patient care delivery. The number of monitored indicators, as determined by the laboratory director, must be consistent with the laboratory's scope of service. Special function laboratories may monitor fewer indicators; full-service laboratories must monitor multiple aspects of the testing process appropriate to their scope of service.

The following key quality indicators have been commonly used to measure, track, and trend laboratory performance over a period of time. The CAP does not require monitoring of any particular indicator, with the exception of indicators that are required in other checklists (eg, TRM.42060, Transfusion Reaction Monitoring transfusion reaction rates).

- *Patient/Specimen Identification: Percent of patient wristbands with errors (ie, mislabels), percent of specimens with patient labeling errors (ie, mislabels), or percent of results with identification errors*
- *Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer*
- *Specimen Acceptability: Percent of specimens received that are suitable for testing*
- *Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered. This may include orders of a "stat" priority (eg, emergency department or intensive care unit specimens), or routine priority, to include the percent of specimens with turnaround time that falls within an established limit (eg, the time that represents the 90th or 95th percentile of turnaround times or less than 30 minutes).*
- *Troponin Turnaround Time: Specific clinical stat turnaround time metrics (eg, order to result availability, specimen collection to result availability).*

- *Critical Result Reporting: Percent of critical results with written record that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time*
- *Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents*
- *Corrected Reports – General Laboratory: Percent of reports that are corrected*
- *Amended Reports – Anatomic Pathology: Percent of reports that are amended*
- *Surgical Pathology/Cytology Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type*
- *Blood Component Wastage: Percent of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue*
- *Blood Culture Contamination: Percent of blood cultures that grow microorganisms that are highly likely to represent contaminants*
- *Laboratory Test Utilization: Percent of tests (or a test) that appear to be redundant, excessive or noncontributory to good patient care.*

The CAP Quality Management Program Tools and publications through the Archives of Pathology provide information regarding definitions of quality indicators and demonstrate statistically valid peer-group performance standards. Publications can be downloaded from cap.org at the following link: https://www.cap.org/laboratory-improvement/quality-management-programs.

Benchmark information on commonly used quality indicators is available in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Quality Management.

Evidence of Compliance:
- ✓ Listing of quality indicators that address all phases of testing and are appropriate for the scope of testing and laboratory services **AND**
- ✓ Defined targets for evaluating quality indicator monitoring data **AND**
- ✓ Quality indicator monitoring data and evaluation at laboratory defined frequency, including comparison against targets based on benchmark data (where available)

GEN.20318 Corrective and Preventive Action **Phase II**

The QMS includes processes for recording corrective and preventive actions taken for non-conforming events (errors and incidents) and quality indicators that do not meet defined targets, and evaluating the effectiveness of the actions taken.

Evidence of Compliance:
- ✓ Records of corrective and preventive actions and effectiveness evaluation

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

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

Evidence of Compliance:
- ✓ Records of personnel and patient complaints (if any) with appropriate follow up

GEN.20326 Assessment of the QMS Implementation **Phase II**

For laboratories that have been CAP accredited for more than 12 months, the QMS is implemented as designed and is assessed at least annually for effectiveness.

NOTE: The QMS must include an appraisal of the following activities:
- *Performance of quality indicators*
- *Follow-up of issues, including non-conformances, requiring corrective and preventive action (when needed)*

- *Actions taken when concerns about quality and safety are reported*
- *Effectiveness of actions taken when quality indicators do not meet targets*

The laboratory must determine whether quality indicators are retained or retired based on their performance, effectiveness of any corrective and preventive measures taken, and how critical they are to patient care. The selection of new monitors must be based on current or potential quality concerns.

Recording of the assessment of the QMS can be achieved by different mechanisms, such as an annual written report or quality management committee meeting minutes. Results of the assessment must be communicated to appropriate laboratory personnel and key stakeholders.

Evidence of Compliance:

✓ Records of effectiveness assessment **AND**
✓ Evaluation of quality measurements **AND**
✓ Records of communication of assessment results with appropriate personnel and key stakeholders

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.

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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 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

GEN.20340 Notifications From Vendors **Phase II**

The laboratory manages notifications from vendors of defects or issues with reagents, supplies, instruments, equipment, or software that may affect patient care/client services.

NOTE: Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory must take timely action on those that have the potential to affect testing results or laboratory services. The laboratory must have appropriate processes to address notifications that may be initially received by different departments (eg, purchasing) to avoid delays associated with handoff communications.

Evidence of Compliance:

- ✓ Records of manufacturer's recalls received **AND**
- ✓ Records of follow-up

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GEN.20351 Adverse Patient Event Reporting **Phase II**

The laboratory reports device-related adverse patient events, as required by the FDA.

NOTE: This checklist item does NOT apply to laboratories accredited under the CAP Forensic Drug Testing program. Non-US laboratories are encouraged to comply with this checklist item, either through reporting to the FDA in the US or to their national equivalent.

When information reasonably suggests that any laboratory instrument, reagent or other device (including all instruments in the central laboratory, satellite laboratories, point-of-care testing programs, and accessory devices used for phlebotomy or specimen collection) has or may have caused or contributed to a patient death or serious patient injury, the FDA requires hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report must be made both to the FDA and the device manufacturer.

If the event is serious patient injury, the report may be to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA.

Reports must be submitted on the FDA Form 3500A (or an electronic equivalent) as soon as practical but no later than 10 work days after the individual becomes aware of a reportable event.

The FDA defines “serious patient injury” as one that is life threatening; or results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling, reagents or calibration; or to user error (since the latter may be related to faulty instrument instructions or design). An adverse patient event that may have resulted from inherent limitations in an analytic system (eg, limitations of sensitivity, specificity, accuracy, and precision) is not reportable.*

The laboratory must have written procedures for:

- *The identification and evaluation of adverse patient events*
- *The timely submission of MDR (medical device reporting) reports*
- *Compliance with record keeping requirements.*

A written record of participation in the overall institutional MDR process is required of laboratories that are part of a larger organization (eg, hospital laboratories).

The laboratory (or parent institution, as appropriate) must submit an annual report of device-related deaths and serious injuries to FDA, if any such event was reported during the previous year. Annual reports must be submitted on Form 3419 (for hospital-based laboratories only, or an electronic equivalent) or Form 3500 (for non-hospital-based laboratories) by January 1 of each year. The laboratory or institution must keep records of MDR reports for 2 years.

Additional information is available on the FDA website, at http:/www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

In this context, “labeling” refers to all user instructions provided by the manufacturer.

Evidence of Compliance:

✓ Records of MDR reports for reportable events, if applicable

GEN.20361 CLIA Certificate Type **Phase II**

For laboratories subject to US regulations performing patient testing subject to CLIA, the laboratory has registered with the Centers for Medicare and Medicaid Services (CMS) and obtained a CLIA certificate that corresponds to the complexity of testing performed, as applicable.

NOTE: This requirement does not apply to laboratories that are part of the Department of Defense. Laboratories located in CLIA exempt states, such as Washington and New York, must be able to show that they have obtained a CLIA number, when appropriate.

The CLIA regulations define a laboratory as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Examples of laboratory activities that do not require registration with the CMS for a CLIA number include:

- *Specimen collection*
- *Specimen preparation, including histology, tissue embedding, sectioning, and staining*
- *Forensic testing*
- *Research testing on human specimens where patient-specific results are not reported to the clinician*
- *Drug testing meeting SAMHSA guidelines and regulations*

Laboratories must obtain the CLIA certificate type that corresponds to their highest level of complexity. The CLIA certificate types include:

- *Certificate of Waiver - waived tests only**
- *Certificate of Provider Performed Microscopy (PPM) Procedures - testing performed by a physician, midlevel practitioner or dentist for specific microscopy procedures (moderate complexity) during the course of a patient's visit*
- *Certificate of Registration - nonwaived testing (moderate or high complexity) prior to initial laboratory inspection*
- *Certificate of Compliance - nonwaived testing with inspection by the State Department of Health (CLIA inspection)*
- *Certificate of Accreditation - nonwaived testing with inspection by a CMS-approved accrediting organization, such as the CAP's accreditation programs.*

For more information on the CMS requirements for CLIA certificates and types of CLIA certificates, refer to Appendix C of the CMS Interpretive Guidelines for Laboratories (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html).

**Any modification from the manufacturer's instructions changes the test classification to nonwaived and requires a different type of CLIA certificate.*

GEN.20374 National/Federal/State/Local Regulations **Phase I**

The laboratory complies with applicable national, federal, state (or provincial), and local laws and regulations.

NOTE: Applicable national, federal, state (or provincial), and local requirements may include but are not limited to the following areas:

- *Tissue handling*
- *Handling radioactive materials*

- *Shipping infectious or diagnostic materials*
- *Reporting infectious disease testing results*
- *Personnel qualifications*
- *Retention of specimens and records*
- *Hazardous waste disposal, storage of flammable materials*
- *Fire codes*
- *Medical examiner or coroner jurisdiction*
- *Legal testing*
- *Acceptance of specimens only from authorized personnel*
- *Handling controlled substances*
- *Patient consent for testing*
- *Confidentiality of test results*
- *Donation of blood*

The checklists contain specific requirements on these areas.

For biorepositories, laws and regulations may also include, as applicable:

- *Storage and handling of select agents*
- *Storage of bulk fuels and other hazardous materials (eg, diesel and liquid nitrogen)*
- *Use of material transfer agreements.*

The laboratory may obtain information on applicable laws and regulations from multiple sources, including hospital management, state medical societies and state departments of health.

GEN.20375 Document Control **Phase II**

The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation.

NOTE: This includes documents relating directly to laboratory testing, as well as others, such as quality management, safety, specimen collection, personnel, and laboratory information systems. The document control system must ensure that only current policies, procedures (including derivative documents such as card files or similar systems that summarize key information for quick reference at the workbench), and forms are in use and that records for approval, review, and discontinuance are available. Discontinued documents must be appropriately archived and removed from general access.

The document master files must be securely stored in a manner that prevents loss, damage, or unauthorized access. Documents needed for functioning of the laboratory must be backed up in a manner that allows access to authorized users in case of power or network system outages (eg, paper-based system or electronic system with emergency power).

It is recommended that the laboratory maintain a control log listing all current policies, procedures, and forms with the locations of copies. The control log may contain other information as appropriate, such as dates when policies and procedures were placed in service, schedule of review, identity of reviewer(s), and dates when policies and procedures were discontinued and/or superseded.

Additional requirements regarding procedure manuals are found in the All Common Checklist, and in this checklist in the Collection Manual, Computer Services and Safety sections.

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GEN.20377 Record and Material Retention - General Laboratory **Phase II**

Laboratory records and materials are retained for an appropriate time.

NOTE: Policies for retention of records and materials must comply with national, federal, state (or provincial), and local laws and regulations and with the minimum retention periods listed in

the table below, whichever is most stringent. For testing on minors (under the age of 21), stricter state regulations may apply.

More specific requirements for certain laboratory records are found in the Anatomic Pathology (ANP.12500, ANP.29670, ANP.33500, ANP.36125), Biorepository (BAP.13740), Cytopathology (CYP.02100, CYP.06600, CYP.06900), Cytogenetics (CYG.32700), Flow Cytometry (FLO.23706), Molecular Pathology (MOL.35870, MOL.49640), Reproductive Laboratory Medicine (RLM.12466), and Transfusion Medicine (TRM.32250) Checklists.

Type of Record/Material	Retention Period
General Records	
Specimen requisitions (including the patient chart or medical record if used as the requisition)	2 years
Accession records	2 years
Quality management records	2 years
Test method validation/verification records	Length of time the test is in use, plus 2 additional years
Proficiency testing records	2 years
Policies and procedures	At least 2 years following discontinuance
Quality control records	2 years
Individualized Quality Control Plan (IQCP) including risk assessment and supporting data, and approval of quality control plan	Length of time the test is in use, plus 2 additional years
IQCP ongoing quality assessment data	2 years
Instrument/equipment maintenance* and function check records (including temperature charts)	2 years
Chain-of-custody collection, receipt, accessioning, and handling records	2 years (or longer as applicable)

Personnel Records	
Competency assessment records	2 years
Training records	2 years

Testing Records	
Instrument printouts (not interfaced with the laboratory computer system) and worksheets***	2 years
Patient test results and reports, including original and corrected reports, and referral laboratory reports	2 years
Direct-to-consumer testing results, including reference intervals	10 years

Laboratory Computer Services	
Computer system validation records	Length of time the system is in use, plus 2 additional years
Records of changes to software, the test library, and major functions of laboratory information systems	Length of time the system is in use, plus 2 additional years
Autoverification rules	At least 2 years following discontinuance
Ongoing computer system checks (eg, calculation verification)	2 years

Patient Specimens (stored under appropriate conditions)	
Serum and plasma	48 hours; exceptions may be made at the discretion of the laboratory director**
Citrated plasma	At the discretion of the laboratory director (see HEM.36940)
CSF, and body fluids (except urine)	48 hours
Whole blood specimens, including blood gas specimens	At the discretion of the laboratory director
Urine	24 hours; exceptions may be made at the discretion of the laboratory director
Extracted DNA/RNA	At the discretion of the laboratory director

Clinical Pathology Slides	
Blood films	7 days
Permanently stained body fluid slides	7 days
Permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles)	7 days

** Laboratories may wish to retain instrument maintenance records for longer than the two-year requirement (eg, for the life of the instrument), to facilitate troubleshooting.*

*** Longer storage requirements may be necessary for patients admitted for suspected drug overdoses. The preferred specimens for most toxicological methods include a urine specimen and a gray top tube with the anti-coagulants potassium oxalate and sodium fluoride collected soon after hospital admission; however, any serum specimen from admission is acceptable. The CAP suggests (but does not require) retaining such specimens for 30 days after presentation to the hospital or at least 48 hours after hospital discharge or death. Specimens collected post-mortem may be inadequate to determine the cause of death if the patient was hospitalized or underwent resuscitative efforts.*

**** For data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., as long as there is a readable electronic record of the data for at least two years. Manual computer entry of patient result data from worksheets, printouts, etc. requires retention of all worksheets, printouts, etc. for at least two years (digitized or photographic images are acceptable). For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.*

GEN.20425 Record and Material Retention Policy **Phase II**

The laboratory has provisions to ensure that all records, slides, blocks, and tissues are retained and available for appropriate times should the laboratory cease operation.

GEN.20430 Verification of Copies of Records Prior to Destruction **Phase II**

The laboratory ensures that laboratory records (eg, patient reports, worksheets, quality control records) being converted onto another medium for storage and retention are verified for accuracy, legibility, and completeness before the original record is destroyed.

GEN.20450 Correction of Laboratory Records **Phase II**

The laboratory makes corrections to laboratory records (eg, quality control data, temperature logs, and intermediate test results or worksheets) using appropriate techniques.

NOTE: The laboratory must have a written procedure that defines how to make corrections to both paper and electronic laboratory records. Laboratory records and changes to such records must be legible and indelible. The techniques used must meet the following criteria:

- *Original (erroneous) entries must be visible (ie, erasures and correction fluid or tape are unacceptable) or accessible (eg, audit trail for electronic records).*
- *Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit.*

This requirement does not apply to changes to patient reports (refer to GEN.41310).

Evidence of Compliance:

✓ Records of corrections to laboratory records

GEN.23584 Interim Self-Inspection **Phase II**

The laboratory has conducted a thorough interim self-inspection and has performed and recorded corrective actions for all deficiencies.

NOTE: CAP-accredited laboratories are required to complete an interim self-inspection at the start of the second year of the laboratory's two-year accreditation cycle, unless an exception is granted by the CAP. It is an important aspect of continuing education, laboratory improvement, and continuous compliance.

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

Laboratories must retain records of the CAP self-inspection, as well as the corrective action for deficiencies, as part of the QMS. The laboratory director's signature on the CAP's Self-Inspection Verification form alone is not sufficient to meet this requirement.

Evidence of Compliance:

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

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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 or designee). Appropriate evidence of review includes both the reviewer's signature or initials and the review date.

SPECIMEN COLLECTION, HANDLING, AND REPORTING

Specimen collection, handling, and results reporting are critical. Specific instructions for the proper collection and handling of specimens must be made available to laboratory personnel and to anyone collecting patient test materials that are sent to the laboratory.

SPECIMEN COLLECTION INSTRUCTIONS

GEN.40016 Specimen Collection Procedure Review **Phase II**

There are records of review of the specimen collection/handling procedures by the current laboratory director or designee at least every two years.

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GEN.40032 New Specimen Collection Procedure Review **Phase II**

The laboratory director reviews and approves all new specimen collection and handling procedures, as well as substantial changes to existing procedures before implementation.

NOTE: Current practice must match written procedures.

For laboratories not subject to US regulations, this review and approval may be performed by a designee who meets CAP director qualifications.

GEN.40050 Distribution of Specimen Collection Manuals **Phase I**

The specimen collection manual is available at all locations where specimens are collected.

NOTE: Locations include areas within the hospital (phlebotomy draw stations, nursing stations, operating room, emergency room, endoscopy and interventional radiology, and out-patient areas) and to areas outside of the hospital (eg, physician offices or other laboratories).

It is acceptable for this information to be electronically available to users rather than in print format; there is no requirement for a paper-based specimen collection manual. Electronic manuals have the advantage of more accurately reflecting current requirements.

GEN.40100 Specimen Collection Manual Elements - Clinical Pathology Specimens **Phase II**

The specimen collection manual for clinical pathology specimens includes instructions for all of the following elements, as applicable:

1. **Preparation of the patient**
2. **Special timing for collection (eg, creatinine clearance)**
3. **Type of collection container and amount of specimen to be collected**
4. **Phlebotomy draw order**
5. **Types and amounts of preservatives or anticoagulants, including instructions for fill volume and proper mixing**
6. **Special handling between time of collection and time received by the laboratory (eg, refrigeration, immediate delivery)**
7. **Proper specimen labeling**
8. **Appropriate clinical data, when indicated**

NOTE: A variety of tests in clinical pathology require specific clinical information (eg, maternal AFP screening, TDM peak and trough measurements, and antibiotic therapy) or special instructions for collection, preservation, and storage (eg, timed or 24-hour urine specimens).

Instructions for the collection of blood specimens for alcohol testing must include proper skin preparation and the use of appropriate preservatives.

GEN.40115 Specimen Collection Manual Elements - Surgical Pathology and Cytopathology Specimens **Phase II**

The specimen collection manual for pathology specimens includes instructions for all of the following elements, as applicable:

1. **Preparation of the patient**
2. **Special timing for collection**
3. **Type of collection container and amount of specimen to be collected**
4. **Types and amounts of fixatives (eg, 10% neutral buffered formalin) or special media (eg, RPMI for flow cytometry), as appropriate, including instructions for fill volume and proper mixing**
5. **Special handling and transport of specimens (eg, triaging of tissue especially if limited need for refrigeration, immediate delivery)**

6. **Proper specimen labeling**
7. **Appropriate clinical data, when indicated.**

NOTE: Written instructions must be available for handling all applicable tissue and cytologic specimens, including biopsies, resections, PAP tests, sputum washings, brushings, body fluids, fine needle aspirations, etc. Instructions must include proper fixation of slides and tissue specimens.

For fixation of specimens in formalin, specimens must be fully submerged with the optimal formalin to approximate specimen volume of 10:1 or higher, or if not feasible (eg, large specimens) at least 4:1.

Because of the importance of clinical information in the practice of surgical pathology and cytopathology, pertinent clinical information for these specimens must be available to the laboratory.

GEN.40125 Handling of Referred Specimens **Phase II**

For specimens sent to referral laboratories, the referring laboratory properly follows all requisition, collection and handling specifications of the referral laboratory.

NOTE: Pre-analytic variables must be closely controlled to maintain specimen integrity. These include specimen temperature, use of preservatives, transport time, and the interval before separation of blood cells from serum/plasma. It may also be necessary to collect specific patient information required by the testing laboratory (eg, clinical information for cytopathology and surgical pathology, gestational age for prenatal neural tube defect screening, bleeding history for specialized coagulation assays).

Laboratories must follow specific collection requirements for the following types of testing:

- *Coagulation and liquid biopsy (eg, EDTA or cell stabilization tubes) - proper filling of the collection tube, the use of waste tubes, and flushing of lines, if blood is drawn through an indwelling line.*
- *Surgical pathology and cytopathology - types and amounts of fixatives (eg, 10% neutral buffered formalin) or special media (eg, RPMI for flow cytometry), as appropriate (including instructions for fill volume and proper mixing), and handling and transport of specimens (eg, full immersion of specimens in fixative, with the optimal volume of formalin to achieve a formalin to specimen volume of 10:1 or higher, or if not feasible (eg, large specimens) at least 4:1; triaging of tissue especially if limited; need for refrigeration or immediate delivery). For breast tissue pathology specimens removed for lesions clinically suspicious for malignancy, the cold ischemia (time of removal of the tissue from the patient to time placed in fixative) and total fixation time must be recorded and submitted to the referral laboratory.*
- *Molecular-based testing - special handling requirements to prevent specimen loss, alteration, or contamination.*
- *Twenty-four-hour urine testing - special preservatives for specific tests.*
- *Microbiology - timing of specimen collection, collection techniques, and selection of appropriate collection devices and transport media.*
- *Newborn screening - specimen collection, application and drying of blood spots, and submission of specimens to the referral laboratory. The designated newborn screening laboratory's instructions must be followed and be in compliance with the most recent edition of the CLSI Document NBS01 and state or local regulations. Specimens must be transported after they are dry and no later than 24 hours after collection or following the instructions provided by the designated newborn screening laboratory. Delays in specimen transportation from the collection facility to the testing laboratory may compromise the integrity of the specimen and results and could critically impact the newborn.*

SPECIMEN COLLECTION AND LABELING

Accurate and precise laboratory data are dependent on properly collected clinical specimens.

GEN.40460 Specimen Collection Supplies **Phase II**

Specimen collection supplies such as blood collection tubes and collection devices (eg, heel lancets, culture swabs, and transport media) are used within their expiration date and stored per manufacturer's instructions.

NOTE: For newborn screening collection cards, if the expiration date is not printed on the individual cards, another mechanism, such as serial number, may be used for tracking.

GEN.40470 Specimen Collection Training **Phase II**

There are records that all personnel collecting specimens have been trained in collection techniques, including the proper selection and use of equipment/supplies, and are knowledgeable about the contents of the specimen collection procedures.

NOTE: This applies to laboratory personnel, including those at remote sites that are owned and operated by the laboratory.

It applies to all personnel who collect and test samples under the laboratory's CAP number, such as for point-of-care testing and for blood gas analysis. It does not apply to the collection of specimens sent to the laboratory by hospital personnel or from outside sources, although this should be encouraged where possible.

All types of specimen collection techniques (eg, phlebotomy, capillary, arterial, in-dwelling line, phlebotomy during intravenous infusion), as well as non-blood specimens, must be included in the training in accord with the individuals' duties. Phlebotomy training must include proper specimen mixing and the correct order of draw. If the laboratory uses prepackaged kits for specimen collection, any special instructions that accompany the kit must be part of the training.

GEN.40490 Patient Identification **Phase II**

The individual collecting the specimen positively identifies the patient before collecting a specimen and labels the specimen in the presence of the patient.

NOTE: Personnel must confirm the patient's identity by checking at least two identifiers before collecting a specimen. For example, an inpatient's wristband may be checked for name and unique hospital number; an outpatient's name and birth date may be used. The patient's room number may not be used as an identifier. Patient identity should be verified by asking patients to identify themselves, when it is practical to do so.*

The laboratory procedures for patient identification must include procedures for verifying identity for patients who have hearing or speech impairments, or who share no common language with the specimen collector. This may include using physical forms of identification (driver's licenses, etc.), companions accompanying the patient, translators, or other members of the health care team personally familiar with the patient (nurses, translators, etc.).

The intent of this requirement is to ensure a written, consistently followed system for correct patient and specimen identification at the point of collection.

**For example, verbal verification is not necessary if obtaining the services of a translator would delay specimen collection.*

GEN.40491 Primary Specimen Container Labeling **Phase II**

All primary specimen containers are labeled with at least two patient-specific identifiers.

NOTE: A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage. Data files received from other laboratories for analysis are considered a specimen and must contain acceptable patient identifiers. Criteria for acceptable specimen labeling and the handling of sub-optimal specimens must be defined.

Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, social security number, requisition number, accession number, unique random number. A location (eg, hospital room number) is not an acceptable identifier. Identifiers may be in a machine-readable format, such as a barcode.

For prepared slides submitted to the laboratory, if the slides are labeled with only one identifier, they must be securely submitted in a container labeled with two identifiers.

In limited situations, a single identifier may be used if it can uniquely identify the specimen. For example, in a trauma situation where a patient's identification is not known, a specimen may be submitted for testing labeled with a unique code that is traceable to the trauma patient. Other examples may include forensic specimens, coded or de-identified research specimens, or donor specimens labeled with a unique code decryptable only by the submitting location.

Obtaining uniform compliance with this requirement may be difficult when specimens are collected by non-laboratory personnel. Potential strategies include: 1) Providing a list of acceptable identifiers to all specimen collectors; 2) Communicating with specimen collectors regarding the importance of this requirement; and 3) Following up with specimen collectors when inadequately labeled specimens are received. Communication and follow-up may be through QM reports, written memoranda, phone calls, visits by client service personnel, or other means of disclosure.

Evidence of Compliance:

- ✓ Specimen collection procedures with defined labeling specifications

GEN.40492 Specimen Label Correction **Phase II**

The laboratory follows a written policy regarding correction of information on specimen labels.

NOTE: If laboratory personnel become aware of a potential error in patient identification or other information (eg, initials of individual collecting the specimen, date/time of collection) on a specimen label, best practice is to recollect the specimen. However, there may be circumstances when recollection is not possible or practical (eg, for specimens that are impossible or difficult to recollect, such as cerebrospinal fluid). The laboratory should define the circumstances under which correction of the information on specimen labels is permitted. A record of all such corrections should be retained. The laboratory should investigate errors in specimen labeling, and develop corrective action as appropriate, including education of personnel who collect specimens.

Evidence of Compliance:

- ✓ Records of corrections to specimen labels and corrective action

GEN.40493 Specimen Labeling for Pretransfusion Testing **Phase II**

All blood specimens collected for pretransfusion testing are labeled at the time of specimen collection in the presence of the patient with:

1. **Patient's first and last name**

2. **Unique identification number**
3. **Date of collection**
4. **A method to identify the individual collecting the specimen**

NOTE: Blood specimens collected for pretransfusion testing must be positively and completely identified and labeled before leaving the patient. Acceptable practices for positive identification of patient and blood specimen labels must be defined in the procedure manual and may include visual inspection and/or an electronic system to read the identifying information contained in bar codes or radio-frequency identification (RFID) microchips or the patient's wristband. Acceptable practices for generating specimen labels must be defined in the procedure manual and may include electronic devices utilizing information encoded in bar codes or RFID microchips. There must be a dependable method to identify the individual who collected the blood specimen, such as initials or another identifier on the tube, or an electronic record.

Evidence of Compliance:

- ✓ Properly labeled blood specimens for pretransfusion testing **AND**
- ✓ Records identifying the individual collecting pretransfusion testing specimens

GEN.40499 Specimen Collection Feedback **Phase I**

There is a mechanism to provide feedback to the collectors of specimens on issues relating to specimen quality and labeling.

NOTE: The accuracy of an analytic result depends upon the initial quality of the specimen, including adherence to pre-analytic parameters for the ordered test. Proper collection techniques are essential.

Evidence of Compliance:

- ✓ Records of communication of specimen collection issues, such as QM reports, staff meeting minutes **OR** records of employee counseling

GEN.40501 Phlebotomy Adverse Reaction **Phase II**

The laboratory has procedures to care for patients who experience adverse reactions from phlebotomy.

NOTE: Minor adverse reactions include hematomas, abrasions, nausea, and fainting. Serious injuries include vomiting, nerve damage, seizures and injuries. Training of phlebotomists should emphasize injury prevention. Serious reactions must be recorded in an incident log.

Evidence of Compliance:

- ✓ Phlebotomist training records

SPECIMEN TRANSPORT AND TRACKING

This section applies to laboratories that send specimens to referral or other laboratories for testing, whether or not the specimen collection is performed by the laboratory staff. It also applies to referral laboratories that receive specimens from other laboratories or remote locations outside of the facility for testing.

While transportation of clinical specimens may not be the responsibility of personnel under the control of the laboratory director, issues of tracking and specimen quality must be addressed to ensure quality laboratory results.

GEN.40511 Specimen Tracking/Labeling **Phase II**

All specimens are properly packaged and labeled to indicate the general nature of the materials transported.

GEN.40512 Infectious Material Packing/Shipping **Phase II**

The laboratory packages and ships infectious material in accordance with applicable national, federal, state (or provincial), and local laws and regulations.

GEN.40515 Transport Personnel Training **Phase II**

Transport personnel are trained in appropriate safety and packaging procedures suitable to specimen type and distances transported, including training for personnel involved in packaging and shipping infectious substances.

NOTE: Training should include issues such as adherence to regulations for transport of biohazards, use of rigid containers where appropriate, temperature control, notification procedures in case of accident or spills, etc.

All personnel who package infectious specimens for shipment must satisfactorily complete training in these requirements. Federal and international regulations mandate the proper packaging and transportation of infectious substances, also termed "etiologic agents." It is the laboratory's responsibility to determine whether specimens that are to be shipped are subject to the regulations, or are exempt. For US laboratories, specific requirements are set forth by the US Public Health Service, the US Department of Transportation and the US Postal Service. These apply to domestic transportation by land, air or sea, and to international air transportation. Recurrent training is required every 3 years. The laboratory should check with its local department of transportation or state health department for any recent revisions to these requirements.

Laboratories outside of the US must comply with their national, state or provincial, or local laws and regulations.

These requirements for packaging and shipping of infectious substances do not apply to private couriers.

The laboratory may send personnel to courses for training, or may obtain materials to train its personnel in-house. Resources for training are available from many sources, including state health departments, vendors of shipping materials, and the CDC National Laboratory Training Network (NLTN).

Evidence of Compliance:

✓ Records of training for all personnel involved in transport of specimens

GEN.40530 Specimen Tracking **Phase II**

For specimens submitted to the laboratory from remote sites, there is a tracking system and record to ensure that all specimens are actually received.

NOTE: Records should include time of dispatch and receipt, as well as condition of specimens upon receipt. An example of an acceptable tracking system is submission of a packing list (prepared by the client or courier) with each batch of client specimens, which may be checked against the specimens received by the laboratory. Some laboratory tests (eg, coagulation assays) have limitations on time and temperature conditions between collection and analysis. This requirement applies to couriers/transportation systems that are within the laboratory organization or are contracted by it. It does not apply to couriers unrelated to the laboratory.

Evidence of Compliance:

✓ Specimen shipping/transport logs **AND**

- ✓ Records of follow up for specimens not received

GEN.40535 Specimen Transport QM **Phase I**

There is a process for monitoring the quality of submitted specimens, correcting problems identified in specimen transportation, and improving performance of clients or sites that frequently submit specimens improperly.

Evidence of Compliance:

- ✓ Records of corrective action **OR** communications with clients that frequently submit specimens incorrectly

GEN.40545 Newborn Screening Specimen Tracking **Phase I**

For specimens being submitted to a remote testing laboratory for newborn screening for congenital disorders, there is a tracking system and records to ensure that all specimens are submitted in compliance with timing requirements and that a result or other appropriate notification is received indicating that the specimens were actually received.

NOTE: Tracking records should include time of dispatch and condition of specimens upon submission. An example of an acceptable tracking system is the use of a packing list (prepared by the submitting site or courier) with each batch of specimens that is checked against the specimens received by the remote testing laboratory. Newborn screening laboratory specimens have limitations with time and humidity conditions between collection and analysis. This requirement applies to couriers/transportation systems that are part of the laboratory organization and to outside courier systems.

Evidence of Compliance:

- ✓ Records showing results/notifications received on all specimens **AND**
- ✓ Records of follow up for specimens not received at the remote laboratory

BLOOD CULTURE SPECIMEN COLLECTION FOR REFERRAL ONLY

NOTE: This checklist section applies to laboratories that perform only blood culture collection using media provided and quality controlled by another laboratory.

The Microbiology Checklist must be used to inspect laboratories that order blood culture media directly from the manufacturer or supplier and/or laboratories that perform any level of blood culture testing.

*****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 (it is not necessary for the referral laboratory to provide the data used to develop the IQCP). The director of the 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

GEN.40570 Blood Culture Collection **Phase II**

Sterile techniques for drawing and handling of blood cultures are defined, made available to individuals responsible for specimen collection, and practiced.

GEN.40580 Blood Culture Contamination **Phase II**

The laboratory monitors blood culture contamination rates and has established an acceptable threshold.

NOTE: The laboratory must determine and regularly review the number of contaminated cultures. The laboratory may request this data from the referral laboratory or may determine it on their own based on review of reported data and patient records.

Tracking the contamination rate and providing feedback to units and persons drawing cultures has been shown to reduce contamination rates. Other measures for consideration in monitoring blood culture contamination include the types of skin disinfection used, line draws, and the use of diversion devices.

The threshold may be established in collaboration with other relevant institutional groups (eg, infection prevention). The laboratory must perform and record corrective action if the threshold is exceeded.

Evidence of Compliance:
- ✓ Records of contamination rates and corrective action if threshold is exceeded **AND**
- ✓ Records of feedback to responsible parties

GEN.40590 Blood Culture Volume **Phase I**

The laboratory monitors blood cultures from adults for adequate volume and provides feedback on unacceptable volumes to blood collectors.

NOTE: The laboratory may request this data from the testing laboratory or may determine it from its own evaluation of specimens.

Larger volumes of blood increase the yield of true positive cultures. The volume collected must be in accordance with manufacturer instructions (in most systems it is 20 mL), but smaller volumes may be recommended in some systems.

Evidence of Compliance:
- ✓ Records of monitoring of volume at a defined frequency **AND**
- ✓ Records of feedback to responsible parties

REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/PROCESSING

GEN.40725 Requisition Data Entry **Phase II**

Test requisition data elements are entered accurately into the laboratory information or record system.

NOTE: Data elements include patient demographic data; the name and location of the individual or entity ordering the test, as well as other elements needed for the final report (see GEN.41096). The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries. For test orders crossing an interface to the LIS, requirements for interface integrity apply.

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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.

GEN.40825 Specimen ID **Phase II**

There is a system to positively identify all patient specimens, specimen types, and aliquots at all times.

NOTE: Each specimen container must identify the patient uniquely. This may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory, so long as all primary collection containers and their aliquots have a unique label which one can audit back to full particulars of patient identification, collection date, specimen type, etc. Practical considerations of container size may limit the extent of such details. There must be an appropriate, consistently applied accessioning system.

GEN.40900 Specimen Date Received **Phase II**

The date (and time, if appropriate) that the specimen was received by the laboratory is recorded.

GEN.40930 Authorized Requestor **Phase I**

The laboratory has a mechanism to ensure that specimens are analyzed only at the request of an authorized person.

NOTE: The laboratory must perform tests only at the written or electronic request of an authorized person. In some US states and other countries, individuals may order some laboratory tests without a physician's referral (direct-to-consumer testing).

GEN.40935 Test Order Read Back **Phase II**

Personnel receiving verbal or phone orders read back the entire order to verify accuracy of transcription.

GEN.40938 Unclear Test Order **Phase I**

The laboratory confirms test orders that may be unclear (eg, orders using non-standard or non-specific terms).

GEN.40942 Specimen Container Analytic Interference **Phase II**

The laboratory director or designee evaluates significant changes to specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed and approves them for use.

NOTE: Significant changes include new container types, a different container type (eg, a plain container to one with an additive), and when changing to a different vendor. To ensure that the specimen containers do not contribute to analytic interference, the laboratory director or designee must review clinical literature, as available, and evaluate information from specimen collection container and instrument/method manufacturers. Based on the information reviewed and the test systems that will be impacted, the laboratory director or designee determines whether verification by the laboratory is indicated.

Manufacturers of collection containers must perform studies to demonstrate safety and efficacy of the product prior to marketing their products. However, it is not feasible for manufacturers to evaluate all assays on all instrument and methods. The CLSI Guideline GP34-A, Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, recommends performing a comparative tube evaluation when changing to a different type of tube (eg, gel, additive, different vendor). A sample protocol for end user evaluation is provided in the CLSI guideline.

For some analytes it may be necessary to evaluate the effectiveness of the specimen collection containers to accurately maintain analyte stability over time.

Evidence of Compliance:

- ✓ Records of specimen container evaluation for analytic interference with approval for use

The following two requirements apply to laboratories that have a centralized specimen processing area:

GEN.41017 Centrifuge Operating Speeds **Phase II**

The operating speeds of centrifuges are safely checked at least annually.

NOTE: For centrifuges with a safety mechanism preventing the opening of the lid while in operation, the checks of rpm should be performed only by an authorized service representative of the manufacturer or an appropriately trained clinical engineer.

Evidence of Compliance:

- ✓ Records of verification of operating speeds at least annually

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.

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.*

RESULTS REPORTING AND REFERRAL OF TESTING

The laboratory must provide useful clinical data. Data must be legible, accurate, reported in clearly designated units of measurement, and promptly reported to persons authorized by law to receive and use medical information.

A referral laboratory is any outside location to which the referring laboratory submits specimens or material for testing [CLSI guideline QMS05 3rd ed]. In the requirements that follow, the phrase "referral laboratory" means an independent, external enterprise. The phrase "off-site location" is used when part of the testing essential for a final result is performed at a closely affiliated or satellite laboratory. Off-site locations include offices where images or data files are reviewed and interpreted with frequency (ie, recurrent or on a regular basis). The addition of an electronic signature to a final report is not off-site laboratory testing, nor is the rendering of a consultative opinion that does not involve a specimen submitted for testing.

GEN.41067 Content/Format Report Review **Phase I**

An individual meeting CAP laboratory director qualifications reviews and approves the content and format of paper and electronic patient reports at least every two years.

NOTE: The laboratory director (or a designee who meets CAP qualifications for laboratory director) must review and, at least every two years, approve the content and format of laboratory patient reports (including paper reports, computer screen images, and downtime reports) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff. Further details on review of electronic reports are given in GEN.48500.

GEN.41077 Reporting Outside Test Results **Phase I**

There is a policy for laboratory director (or designee meeting CAP director qualifications) input regarding the integration of outside test results into the institution's patient data systems (eg, laboratory information system (LIS), institutional electronic medical record).

NOTE: At times patient results obtained from sources outside a laboratory (eg, other laboratories, patient-performed testing, wearable sensors) may be considered for integration into the laboratory's primary reporting system (LIS) or the institution's electronic medical record). The laboratory director should be aware of such test results and should be able to recommend integration strategies.

If the outside results are integrated, the report must include the origin of the results.

For reporting of test results obtained from referral laboratories, refer to GEN.41440.

*****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 (printed copies or electronic data) to users and sites where reports are received. The laboratory must ensure that such data is 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 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.

GEN.41300 Report Retention and Retrieval **Phase II**

Copies or files of reports are legible and retained by the laboratory in a manner that permits prompt retrieval of the information.

NOTE: The length of time that reported data are retained in the laboratory may vary; however, the reported results must be retained for that period encompassing a high frequency of requests for the data. In all circumstances, a hospital laboratory must have access to the patient's chart where the information is permanently retained.

GEN.41303 Patient Confidentiality **Phase II**

The laboratory ensures that internal and external storage and transfer of data maintains patient confidentiality and security.

NOTE: Written procedures must address patient confidentially during transfer of data to external referral laboratories or other service providers. This must include cloud based computing (eg, for storage of confidential data), as appropriate

The laboratory must audit compliance with the procedures at least annually.

Evidence of Compliance:

- ✓ Records of patient privacy audit for compliance with the Health Insurance Portability and Accountability Act (HIPAA)

GEN.41304 Patient Data Accessibility **Phase II**

The laboratory ensures that patient data are accessible in a timely manner only to those individuals who are authorized to review test results.

NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. For completed tests, these results must generally be provided no later than 30 days after such a request. Laboratories must also comply with other federal and state laws on patient access to laboratory and pathology results.

Under the CLIA Program and HIPAA Privacy Rule, Patients' Access to Test Reports, only the patient or a personal representative, defined as an individual who has authority under applicable law to make health care decisions for the patient, can be given access to a patient's personal health data. Laboratories must take reasonable steps to verify the identity of the patient and the authority of a personal representative before granting access to an individual's protected health information. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable.

GEN.41306 Analyst Tracking ID **Phase II**

There is a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established.

NOTE: If results are released using autoverification, the system must be capable of identifying those test results that have been autoverified. In addition, the laboratory should be able to identify the technologist responsible for the instrument producing the result, such as through daily bench assignment charts, instrument set-up logs, or electronic audit trail.

GEN.41307 Report Errors **Phase II**

When errors are detected in patient test reports, the laboratory promptly notifies responsible clinical personnel or referring laboratory as applicable and issues a corrected report.

NOTE: Notification should include the department of health or other legal entity as required by local regulations.

For changes to anatomic pathology and cytopathology reports, refer to ANP.12185 and CYP.06475.

Evidence of Compliance:
- ✓ Records of report error notification and corrected report

GEN.41310 Corrected Report **Phase II**

All corrected reports of previously reported, incorrect patient results are identified as corrected, and both the corrected and original data are clearly identified as such.

NOTE: As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the corrected information. The previous information and the corrected information must be identified as such, and the original data must be present in the corrected report (for paper reports), or linked electronically or logically to the corrected information (in electronic reports).

This requirement applies to electronic reports in the laboratory information system and to the data systems interfaced to the laboratory information system either directly or through

middleware or an interface engine (but not to systems that are further downstream in the interface chain).

Displays in an electronic medical record (EMR) downstream from the laboratory should include the original report as well as the corrected report. The report elements listed in GEN.41096 should be included in the EMR.

The correction should add explanatory language if an explanation would be helpful to the user. For example, a comment about transport or sample storage conditions uncovered post-analysis can help frame an original, invalid result.

For changes to anatomic pathology and cytopathology reports, refer to ANP.12185 and CYP.06475.

GEN.41312 Multiple Corrections **Phase II**

When there are multiple sequential corrections of a single test result, all corrections are referenced in sequential order on subsequent reports.

NOTE: When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should be referenced in the patient report.

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

The laboratory ensures communication of diagnoses of infectious diseases of particular significance to the physician or other clinical personnel responsible for patient care and records of those communications are retained.

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

GEN.41325 Newborn Screening Results **Phase II**

The laboratory has a defined process for handling invalid and positive newborn screening results for samples submitted to other laboratories for testing.

NOTE: This requirement applies to the testing of whole blood heel stick samples from the newborn after birth on filter paper collection devices for the routine screening of congenital disorders. Positive results include those results that are outside of the expected range of testing results established for a particular condition. Invalid results include situations where the laboratory is unable to complete the screening process due to an unsuitable specimen, test, or incomplete information. Due to the urgent nature of newborn screening test results, procedures must include a process to track requests for repeat testing so that repeat specimens are submitted within the follow-up/recollection timeframe specified by the testing laboratory.

GEN.41345 Turnaround Time **Phase II**

The laboratory has defined turnaround times (ie, the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and notifies the requester when testing is delayed, as appropriate.

NOTE: This does NOT imply that all instances of delayed reporting for all tests must lead to formal notification of clinical personnel. Rather, clinicians and laboratory must have a jointly agreed upon policy for when such notification is important for patient care.

GEN.41350 Referral Laboratory Selection **Phase II**

The laboratory has a defined process for the selection and evaluation of laboratories to which it refers specimens or materials for testing.

NOTE:

1. *The laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for selecting referral laboratories*
2. *Selection of referral laboratories must be based primarily upon the quality of performance of such laboratories*
3. *Specimens or materials for testing include intermediate processing such as histologic and cytologic processing, preliminary analysis such as flow cytometry, and the use of distributive testing in next-generation sequencing. It also includes the referral of images or data files to an off-site location for interpretation.*

4. *For laboratories subject to US regulations: for tests in disciplines covered by CLIA, specimens and materials for testing must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent (or more stringent) requirements as determined by the CAP and/or the CMS; this includes off-site locations where images or data files are frequently referred for review and interpretation. Laboratories that are part of the Department of Defense* must meet the referral policies of the Clinical Laboratory Improvement Program (CLIP). With respect to patients on research protocols, whose tests are referred to a research laboratory: if those test results are used for patient management decisions, the research laboratory must be CLIA-certified, or meet equivalent requirements as determined by CMS.*
5. *For disciplines that do not require a CLIA certificate (eg, histology specimen processing/ staining, and embryology and associated procedures), laboratories subject to US regulations must refer specimens to a laboratory accredited by CAP or a CAP-accepted organization.**
6. *For non-US laboratories, whenever possible, specimens and materials for testing should be referred to a laboratory accredited by CAP; accredited to an established international standard from a recognized organization; or certified by an appropriate government agency. The inspector may need to exercise judgment with respect to determining if a referral laboratory is acceptable.*
7. *It is the responsibility of the laboratory director or designee to monitor the turnaround time and quality of test results received from referral laboratories.*

**For overseas US military laboratories only, an exception to this requirement is acceptable if both of the following conditions are met:*

1. *Rapid turnaround time (TAT) is required to prevent either a delay in patient treatment/ diagnosis or specimen degradation, and an acceptable TAT cannot be provided by a CAP-accredited or CLIA-certified laboratory.*
2. *The laboratory director has determined that the alternative testing site meets requirements that are equivalent to those of a CLIP or CLIA-certified laboratory as stipulated in the CLIP/ CLIA Manual (11-32(8)c). This assessment must be recorded.*

Evidence of Compliance:

✓ Records of the monitoring of referral laboratory services (eg, problem log, review of reports)

GEN.41430 Referral Laboratory Report Retention **Phase II**

For samples referred to another laboratory, the original or an exact copy of the testing laboratory's report is retained by the referring laboratory.

NOTE: The report may be retained on paper or in electronic format. Exceptions to this requirement may be made under special circumstances or for special categories, such as drugs of abuse or employee drug testing. The laboratory director may make these exceptions.

Evidence of Compliance:

✓ Retained original referral laboratory reports **OR** direct access to referral laboratory reports via electronic transmission from the referral laboratory

GEN.41440 Referral Laboratory Results Reporting **Phase II**

The essential elements of referred test results are reported by the referring laboratory as received from the referral laboratory, without alterations that could affect clinical interpretation.

NOTE: If the laboratory transcribes results from the referral laboratory report, the test result(s), interpretation, and information directly related to the interpretation must be copied as reported by the referral laboratory This does not mandate that the referring laboratory report every word nor retain the exact format of the referral laboratory report. There is no requirement to fully replicate the complete content of the referral laboratory report beyond the results and interpretation. Suggestions for follow-up testing may, for example, be omitted at the discretion of the laboratory director.

Evidence of Compliance:

- ✓ Patient results from the referral laboratory consistent with laboratory-issued patient reports

QUALITY OF WATER AND GLASSWARE WASHING

GEN.41500 Defined Water Types **Phase II**

The laboratory defines the specific type of water required for each of its testing procedures and water quality is tested at least annually.

NOTE: The laboratory should define the type of water necessary for each of its procedures and must have an adequate supply of same. The current edition of CLSI Guideline GP40-A4-AMD defines the following grades of water: Clinical Laboratory Reagent Water (CLRW), suitable for most laboratory procedures; Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications than CLRW; Instrument Feed Water, specified by IVD manufacturers as suitable for use with their measurement systems; and Commercially Bottled Purified Water that may be suitable for certain laboratory procedures.

CLRW is not required if the laboratory is able to record reliable results with an alternate grade of water.

The following specification for CLRW is adapted from this guideline and should be met at time of in-house production:

	CLRW
Maximum microbial content (CFU/mL)	*10*
Minimum resistivity (megohm-cm)	*10 (in-line)*
Particulate matter	*0.22 um filter*

Bacteria may inactivate reagents, contribute to total organic contamination, or alter optical properties of test solutions. Resistivity provides a nonspecific measure of the ion content. Particulate matter includes organic carbon from biofilms and inorganic aggregates that can vary over time, both in nature of the contamination and the effect on the laboratory use.

The CLSI Guideline provides testing information for microbial content and resistivity, as well as total organic carbon; earlier specifications for silicates have been removed. It gives instructions for the preparation of the various types of water. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water.

The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and recorded at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be recorded if water does not meet acceptability criteria.

For CLRW, minimum monitoring includes resistivity and microbiology cultures. Other monitoring criteria, such as pH, endotoxin/pyrogens, silicates and organic contaminants are at the discretion of the laboratory. Testing for these substances must be recorded only if the laboratory finds that they adversely affect specific test methods.

The laboratory must determine the level of testing necessary for other grades of water in use.

Typically, "sterile (pharmaceutical) water" is not manufactured to meet the specifications of CLRW and should not be used as its equivalent.

For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed

to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water.

Evidence of Compliance:
- ✓ Records of water quality testing **AND**
- ✓ Record of corrective action when water quality does not meet specifications

***REVISED** 08/24/2023*
GEN.41770 Glassware Cleaning **Phase II**

When detergent is used for cleaning glassware, the laboratory tests for detergent removal and takes action if detergent residue is detected.

NOTE: Special instructions for micropipettes, cuvettes, acid washing, etc. must be included.

The test to detect detergent removal should be appropriate for the method of washing (eg, glassware washing machine, manual washing). Simple procedures to check for detergent residue include the use of pH paper or bromcresol purple (0.1 g bromcresol purple in 50 mL ethyl alcohol). To use bromcresol purple, pipette approximately 5 cm (2 inches) distilled water into a representative, washed, glassware item. Add two to three drops bromcresol solution. A purple color (high pH) reveals residual detergent. A yellow color indicates satisfactory rinsing.

Evidence of Compliance:
- ✓ Records of detergent residue testing

LABORATORY COMPUTER SERVICES

Multiple types of laboratory information systems (LIS) exist. Traditional systems have a local "host" database (ie, the computer hardware and software) serving the information needs of the laboratory; the laboratory is the only "user." In the current environment, the host is often physically remote from the laboratory and in fact the host may have multiple user laboratories. Many of the Computer Services requirements may apply to host, user, or both, depending on how information services are organized in the laboratory. The laboratory is responsible for ensuring that the provider of host functions meets CAP requirements (see GEN.42195, below).

The requirements in this section do NOT apply to the following:
1. *Desktop calculators*
2. *Small programmable technical computers*
3. *Purchased services such as the Quality Assurance Service or Laboratory Management Index Service of the College of American Pathologists*
4. *Micro computers used solely for word processing, spreadsheets, or similar single user functions*
5. *Dedicated microprocessors or workstations that are an integral part of an analytic instrument*

COMPUTER FACILITY

This section applies to laboratories where the computer facilities are housed.

GEN.42750 Computer Facility Maintenance **Phase I**

The computer facility and equipment are clean, well-maintained and adequately ventilated with appropriate environmental control.

NOTE: The computer facilities should be clean, well maintained and in a location that is environmentally controlled, as required by the most restrictive vendor specifications.

GEN.42800 LIS Fire Equipment **Phase II**

Fire-fighting equipment is available and appropriate for information technology equipment.

NOTE: Acceptable fire-fighting equipment/extinguishers in areas with information technology equipment may include:

1. *Automatic sprinkler systems that are valved separately from other systems*
2. *Gaseous clean agent extinguishers systems*
3. *Listed portable fire extinguishers of carbon dioxide or halogenated agent type*
4. *Listed extinguishers with a minimum rating of 2-A for ordinary combustible material (paper and/or plastics)*
5. *Gaseous agent inside units or total flooding systems when there is critical need, eg, to protect data in process, reduce equipment damage and to facilitate a return to service*

Dry chemical extinguishers are not recommended because of the corrosive damage they cause. In the instance where no other extinguisher is available and there is imminent danger to personnel or property however, a dry extinguisher may be used.

GEN.42900 LIS Power **Phase II**

The computer system is adequately protected against electrical power interruptions and surges.

NOTE: Protection from electrical surges and interruptions must be adequate to prevent loss of data. An uninterruptible power system (UPS) or similar protective device (eg, isolation transformer) must be considered. Periodic testing of this protective equipment to ensure protection of data and proper shutdown of computer equipment is considered best practice.

HARDWARE AND SOFTWARE

*****REVISED** 08/24/2023***
GEN.43022 LIS Testing **Phase II**

Programs are adequately tested for proper functioning when first installed and after any modifications, and the laboratory director or designee has approved the use of all new programs and modifications.

NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications, including assessment after implementation in the live (production) system. Any changes or modifications to the system must be recorded, and the laboratory director or designee must approve all changes, additions and deletions in programs, the test library, and major computer functions before they are released. This applies both to locally installed and remotely hosted software. Testing should include reference intervals, critical values and/or verification limits, and operational rules/algorithms. Rules producing reported patient results or result interpretation are addressed in GEN.43450. Records must be retained for at least two years beyond the service life of the system.

Evidence of Compliance:

- ✓ Records of testing and approval

GEN.43033 Custom LIS **Phase I**

Customized software, and modifications to that software, are appropriately documented and records allow for tracking to identify persons that have added or modified that software.

NOTE: The purpose of the computer program, the way it functions, and its interaction with other programs must be clearly stated. The level of detail should be adequate to support trouble-shooting, system modifications, or additional programming.

GEN.43040 LIS Policy and Procedure Approval **Phase II**

The laboratory director or designee reviews and approves all new LIS policies and procedures, as well as substantial changes to existing documents before implementation.

NOTE: Procedures should be appropriate to the level of use of the system, and must encompass the day-to-day activities of the laboratory staff as well as the daily operations of the Information Technology staff.

GEN.43055 Computer System Training **Phase II**

There are records for training of all users of the computer system initially, after system modification, and after installation of a new system.

NOTE: Review of LIS policies and procedures relevant to the scope of duties must be incorporated into the training.

GEN.43066 Computer Malfunction Notification **Phase II**

Instructions are available in the event of a computer malfunction, including information for contacting a responsible person (eg, Computer System Manager).

SYSTEM SECURITY

The following requirements concern unauthorized users. If a system is vulnerable, steps should be taken to prevent unauthorized access.

GEN.43150 User Authentication **Phase II**

Personnel follow explicit written policies defining who may access the computer system, how the access is obtained, and how the security of access is maintained (eg, inactivated when personnel leave, not posted on terminals).

NOTE: The laboratory must establish security (user) codes to permit only specifically authorized individuals to access patient/client data or alter programs. Policies must prohibit the use of access privileges of others. Examples of best practices include: periodic alteration of passwords by users; minimum character length for passwords; password complexity requirements (eg, a combination of alphanumeric characters); recording of failed log-on attempts with user lock-out after a defined number of unsuccessful log-on attempts.

Access control policies must include physical entry to data center(s) housing the LIS, logging into server(s) operating system hosting the LIS, as well as software system(s) that comprise the LIS, as applicable.

GEN.43200 User Authorization Privileges **Phase II**

Access privileges are used to confine the level of authorized user access to those functions necessary to fulfill job responsibilities.

NOTE: The laboratory must establish user roles and/or policies that define those who may only access patient/client data and users who are authorized to enter results, change results, or alter computer tables or programs. Personnel user rights must be limited to only the level needed to execute assigned responsibilities, also referred to as the "minimum necessary." If data in other computer systems can be accessed through the LIS (eg, pharmacy or medical records), policies must prevent unauthorized access to the data through the LIS to permit only specifically authorized individuals to access patient/client data or alter programs.

GEN.43262 Unauthorized Software Installation **Phase I**

Installation of software on any computer used by the laboratory is controlled.

NOTE: Laboratory computers often serve multiple functions. Many of these computers are connected in a network. The security of the system must be sufficient to prevent the casual user from installing software. Such unauthorized installation may cause instability of the operating system or introduce other unwanted consequences. Many operating systems allow procedures to restrict certain users from installing software.

GEN.43325 Public Network Security **Phase II**

There are network security measures to ensure confidentiality of patient/client data sent over public networks.

NOTE: Patient/client information sent over a public domain, such as the internet, or stored in a cloud environment is considered "potentially public" and may be accessible to unauthorized parties on that network. Systems must be in place to protect network traffic, such as fire walls and data encryption schemes. If such storage is used for patient/client information, encryption at rest and encryption in transit should be implemented to ensure network and data security.

Evidence of Compliance:

- ✓ Records of security parameters

PATIENT/CLIENT DATA

*****REVISED** 08/24/2023***

GEN.43450 Verification of Calculations Producing Patient Results **Phase II**

Calculations that use patient results to produce other reported results are reviewed every two years or when a system change is made that may affect the calculations.

NOTE: This checklist requirement applies to laboratory information systems, middleware, and analyzer calculations modifiable by the user (eg, estimated glomerular filtration rate [eGFR] or interpretive table for female reproductive cycle hormonal levels). This checklist requirement does not apply to preset calculations provided by instruments as results or to age/sex stratified reference intervals that are routinely implemented, such as by an LIS.

More frequent checks may be required for certain specific calculations, as delineated elsewhere in the checklists (eg, INR). When calculations are performed by an LIS shared by multiple laboratories, this review only needs to be done at one location and each individual laboratory must have access to a copy of the review records. However, any calculations specific to an

individual laboratory's methodology must be reviewed by that laboratory and the record of that review must be available.

Evidence of Compliance:
- ✓ Records of validation of calculated test results

GEN.43750 Specimen Quality Comment **Phase II**

The system provides for comments on specimen quality that might compromise the accuracy of analytic results (eg, hemolyzed, lipemic).

Evidence of Compliance:
- ✓ Patient reports

GEN.43800 Data Input ID **Phase II**

There is an adequate system to identify all individuals who have entered and/or modified patient/client data or control files.

NOTE: When individual tests from a single test order (eg, multiple tests with same accession number) are performed by separate individuals and the test result is entered into the LIS, the system must provide an audit trail to record each person involved. For example, a single accession number having orders for electrolytes and a lipid panel may have testing done by two or more individuals. The laboratory should be able to identify the responsible personnel who performed each test and posted the data. This includes sequential corrections made to a single test result. If autoverification is used, then the audit trail should reflect that the result was verified automatically at a given time.

With point-of-care testing, if the individual performing the test is different than the individual entering test data into the LIS, both should be uniquely identified by the system and retrievable by audit trail.

GEN.43825 Result Verification **Phase II**

Manual and automated result entries are verified before final acceptance and reporting by the computer.

NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is checking the result against the reportable range and critical results for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail.

This checklist requirement does not apply to autoverification procedures (see below).

GEN.43837 Downtime Result Reporting **Phase II**

The laboratory ensures reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system.

DATA RETRIEVAL AND PRESERVATION

GEN.43900 Archived Test Result **Phase II**

A complete copy of archived patient test results can be retrieved, including original reference intervals and interpretive comments, including any flags or footnotes that were present in the original report, and the date of the original report.

NOTE: Stored patient result data and archival information must be easily and readily retrievable within a time frame consistent with patient care needs.

GEN.43920 Multiple Analyzer ID **Phase I**

When multiple identical analyzers are used, they are uniquely identified such that a test result may be appropriately traced back to the instrument performing the test.

NOTE: Best practice is to store these data in the LIS.

GEN.43946 Data Preservation/Destructive Event **Phase II**

The laboratory follows written procedures for the preservation of data and equipment in case of an unexpected destructive event (eg, fire, flood, malicious incident), software failure and/or hardware failure, and these procedures allow for the timely restoration of service, including data integrity check.

NOTE: Procedures must 1) be adequate to address scheduled and unscheduled interruptions of power or function; 2) be tested periodically for effectiveness; and 3) include systems to backup programs and data.

These procedures can include, but are not limited to, 1) steps to limit the extent of the destructive event, 2) periodic backing up and storing of information, 3) off-site storage of backup data, and 4) restoring information from backed up media. The procedures should specifically address the recoverability of patient/client information. Changes to hardware and software commonly require review and reevaluation of these written procedures. These procedures must specifically address the physical environment and equipment and are often addressed by the organization's disaster plan.

INTERFACES

GEN.46000 Reference Interval/Units Transmission **Phase I**

As applicable, reference intervals and units of measure for every test are transmitted with the patient result across the interface.

NOTE: The reference interval, including units of measure, may be specific for a given patient result and should be attached to that result such that it will be displayed along with the patient result.

GEN.48500 Interface Result Integrity **Phase II**

The laboratory verifies that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic) when the following occur:

- **Prior to implementation of an interface (pre go-live) and**
- **Whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results.**

NOTE: Verification of accurate data transmission from the LIS to other systems must be performed by reviewing data in the first downstream (or interfaced) system in which the ordering clinician/client (eg, referring laboratory) may be expected to routinely access patient data. If the LIS has separate interfaces to multiple receiving systems in which patient data can be accessed by clinicians, then reports from each receiving system must be validated. However, where multiple sites use the same recipient system (the same installed instance of an electronic medical record system), validation need only occur for the interface at one of the sites and not for each individual site that is served by that single installed system.

Interface validation must include examples of individual results, test packages or batteries, abnormal flags, and results with reference intervals and comments/footnotes. Initial interface validation must include verification that corrected results for clinical laboratory and anatomic pathology results are handled accurately in the receiving system.

Evidence of Compliance:

- ✓ Printed screen shots or other verification records

GEN.48750 LIS Interface Shutdown/Recovery **Phase II**

The laboratory follows procedures for changes in laboratory functions necessary during partial or complete shutdown and recovery of systems that interface with the laboratory information system.

NOTE: These procedures must ensure integrity of patient test data. Procedures must include verifying recovery of interfaced systems, and replacement or updating of data files, as necessary.

PERSONNEL

The laboratory must have personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files must contain records of educational qualifications (eg, copies of diplomas, transcripts, primary source verification reports), laboratory personnel licenses (where required), training and continuing education for each employee. Ideally, these files should be located in the laboratory. If they are retained outside of the laboratory, they must be readily available to the inspector on the day of inspection. The inspector reviews the personnel files using the Laboratory Personnel Evaluation Roster.

Biorepositories use the Biorepository Personnel Roster. There are additional personnel requirements that are applicable only to biorepository personnel in the Biorepository Personnel section.

SECTION DIRECTORS (TECHNICAL SUPERVISORS)/GENERAL SUPERVISORS

This section applies to laboratories performing one or more high complexity tests. The individuals fulfilling these roles must be identified on the CAP's Laboratory Personnel Evaluation Roster.

The term "section director" may be considered synonymous to the technical supervisor in the checklist requirements. The term "supervisor" may be considered synonymous to the general supervisor in the checklist requirements. Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may serve as the section director and general supervisor, and may set position requirements more stringent than defined in the checklist.

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

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

Section 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.*
   - *If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology*
   - *If responsible for clinical pathology must be board certified in clinical pathology*
   - *If responsible for anatomic pathology and/or cytopathology, and clinical pathology, must be board certified in both anatomic and clinical pathology*

OR:

2. *For specialties other than anatomic pathology and 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, biological, 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, biological, 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, 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 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 fill this role if they have done so continuously since December 28, 2024.

More detailed information on technical supervisor qualifications, including specialty and discipline-specific requirements and additional educational pathways for individuals with doctoral, master's, and bachelor's degrees, 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 and in CLIA regulation 42CFR493.1449.

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

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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 have a minimum of one of the following:

1. *Bachelor's degree in a chemical, biological, 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)(3)(ii), with at least two years of training and/or experience in high complexity testing*; or*
3. *Qualified and served as a general supervisor in a CLIA-certified laboratory as of December 28, 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 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 semiannual and annual competency in laboratories performing both moderate and high complexity testing, 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

TECHNICAL AND CLINICAL CONSULTANT

The individuals fulfilling these roles must be identified on the CAP's Laboratory Personnel Evaluation Roster.

Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may also serve as the technical and clinical consultant, and may set position requirements more stringent than defined in the checklist.

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*
- *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, biological, 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, 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

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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 MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required); **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)

ALL PERSONNEL

GEN.54000 Organizational Chart **Phase II**

There is an organizational chart for the laboratory, or a narrative description that describes the reporting relationships among the laboratory's owner or management, the laboratory director, section director(s)/technical supervisor(s), technical consultant(s), clinical consultant(s), and supervisor(s)/general supervisor(s), as appropriate.

*****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

GEN.54200 Continuing Education **Phase I**

There is a functional continuing laboratory education program adequate to meet the needs of all personnel.

GEN.54400 Personnel Records **Phase II**

Personnel records are retained (in electronic or paper format) and readily available for all testing personnel, supervisory personnel, and other laboratory personnel, including all of the following, as applicable:

1. **For nonwaived testing and supervisory personnel, copy of academic diploma, transcript, or primary source verification (PSV) report confirming credentials**
2. **Laboratory personnel license, if required by state, province, or country**
3. **Summary of training and experience**
4. **Certification, if required by state or employer**
5. **Description of current duties and responsibilities as specified by the laboratory director: a) Procedures the individual is authorized to perform, b) Whether supervision is required for specimen processing, test performance or result reporting, c) Whether supervisory or section director review is required to report patient test results**
6. **Records of continuing education**
7. **Records of radiation exposure where applicable (such as with in vivo radiation testing), but not required for low exposure levels such as certain in vitro testing**
8. **Work-related incident and/or accident records**
9. **Dates of employment**

NOTE 1: All items, #1-9 above, apply to nonwaived testing personnel and supervisory personnel (including both laboratory and non-laboratory personnel), as applicable to assigned duties.

For other types of laboratory personnel (eg, phlebotomists, specimen processors, biorepository personnel), items #2-9 apply, as applicable to their assigned duties. These personnel must meet the institution's defined qualifications for the positions held and have appropriate state licensure, where applicable.

NOTE 2: For laboratories subject to US regulations, nonwaived testing and supervisory personnel records must demonstrate that each individual meets the required educational qualifications for the position held.

A state laboratory personnel license specific to the role and specialty of testing may be used instead of a diploma, transcripts, or a PSV report if the laboratory is located in a state that requires laboratory personnel licensure and qualifications are at least as stringent as CLIA (licensure for other disciplines, such as nursing, radiology, or respiratory therapy are not acceptable).

If a diploma or primary source verification (PSV) report does not specify one of the required areas of study (biology, chemistry, etc.) or are for training obtained outside of the US, there must be records showing that qualifications are met using other acceptable means (eg, transcripts, equivalency evaluation).

*The training and qualifications of all personnel trained outside of the US **must** be evaluated to determine equivalency to an education obtained in the United States, with records of the evaluation available in the personnel file. Equivalency evaluations must be performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (http://www.naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org). 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.*

If PSV reports are used, the laboratory must have a defined system for reviewing the reports, with written criteria for acceptance. PSV is typically performed by a third-party agent or company that directly contacts institutions and former employers to verify training and experience, such as diplomas, board certification, licensure, and reported work history. PSV reports confirming the required qualifications may be retained in lieu of obtaining paper copies of these records.

The credentialing systems used by the Department of Veterans Affairs (ie, VetPro Credentialing System) and Department of Defense may be used to document educational qualifications. Records must be available upon request.

While certification of testing personnel by a professional organization, such as ASCP or AMT, is highly desirable, records of the certification alone are not considered adequate to demonstrate that educational qualifications have been met.

NOTE 3: For laboratories not subject to US regulations, laboratories may authenticate educational achievement according to prevailing governmental rules.

Evidence of Compliance:

- ✓ Copies of diplomas, transcripts, equivalency evaluation, or current laboratory personnel licensure (if required) accessible at the laboratory **OR**
- ✓ Policy for use of primary source verification reports, with criteria for acceptance, if used **AND**
- ✓ Primary source verification reports with required elements

*****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, biological, 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 CLIA regulation 42CFR493.1489(b)(3)(ii) (see NOTE 2); or**
   - **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 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, biological, clinical or medical laboratory science, medical laboratory technology, or nursing from an accredited institution; or**
   - **High school graduate or equivalent and meet the requirements defined in NOTE 4; or**
   - **High school graduate or equivalent and completion of an official US military medical laboratory procedures training course of at least 50 week duration and currently hold or have held the 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.

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 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 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: Laboratories in the CAP's Forensic Drug Testing (FDT) accreditation program must meet qualifications 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

Personnel are tested for visual color discrimination.

NOTE: Personnel performing testing or other tasks that require color discrimination should be evaluated for difficulty with visual color discrimination. Evaluation is not required for personnel who do not perform such functions. Evaluation limited to discrimination of those colored items pertinent to the job is sufficient.

Evidence of Compliance:

- ✓ Record of color discrimination testing or functional assessment, if indicated **OR**
- ✓ Documented acknowledgement that testing was performed

GEN.55450 Personnel Training **Phase II**

There are records that all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job.

NOTE: For testing personnel, prior to starting patient/client testing and prior to reporting patient/client results for new methods or instruments, each individual must have training and be evaluated for demonstration of the skills required for proper test performance of pre-analytic, analytic, and post-analytic phases of testing, as applicable, and their ability to work under the expected level of oversight during routine patient testing. The records must cover all testing performed by each individual.

Training records must be retained for a minimum of two years (five years for transfusion medicine). After the initial two-year (or five-year) period, records of successful ongoing competency assessment may be used in lieu of training records to demonstrate compliance with this requirement.

Retraining must occur when problems are identified with personnel performance.

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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. California regulation CCR Title 17 1036.3 states that a waived laboratory 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 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

GEN.55500 Competency Assessment Elements - Nonwaived Testing **Phase II**

The competency of personnel performing nonwaived testing is assessed using all six elements (as applicable) on each test system.

NOTE: Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. The laboratory must identify the test systems that testing personnel use to generate test results, including both primary and back-up methods used for patient testing. If a single test or analyte is performed using different test systems, a separate assessment is required.

A TEST SYSTEM is 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.*
- *It includes instructions, reagents, supplies, equipment and/or instruments required to produce test results.*
- *It may encompass multiple identical analyzers or devices.*
- *It may include multiple tests performed on the same testing platform (eg, analyzer), unless tests have unique aspects, problems, or procedures (eg, pretreatment of specimens prior to analysis. In those situations, competency must be assessed as a separate test system to ensure personnel perform those aspects correctly.*

*The **six required elements** of competency assessment include but are not limited to:*

1. *Direct observations of routine patient test performance, including, as applicable, patient 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*

5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing specimens (eg, de-identified patient specimens) or external proficiency testing specimens*
6. *Evaluation of problem-solving skills.*

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 if they are assessed by an individual qualified to assess competency (GEN.55510). 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).

The following includes examples of how competency assessment can be coordinated with routine practices and procedures:

- *Assessment of the recording of quality control results and instrument maintenance data in element #3 during the monthly supervisory review process of these records.*
- *Assessment of test performance in element #5 during reviews of proficiency testing or alternative performance assessment records.*
- *Assessment of problem-solving skills in element #6 from monthly reviews of corrective action logs where problems with quality control or instrument function were investigated.*

The CAP provides example competency assessment templates, which can be downloaded from cap.org in e-Lab Solutions Suite - Accreditation Resources - Templates.

Evidence of Compliance:

✓ Records of competency assessment reflecting the specific skills assessed for each test system and the method of evaluation

GEN.55505 Competency Assessment Frequency - Nonwaived Testing **Phase II**

The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed.

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:

- *At least semiannually (first assessment within seven months from the start of testing and second assessment no later than 12 months from the start of testing during the first year an individual tests patient specimens (new employees))*
- *At least annually after an individual has performed assigned duties for one year**
- *When problems are identified with an individual's performance.*

**The annual assessment of competency can be performed throughout the entire year to minimize impact on workload.*

Records of competency assessment may be retained centrally within a healthcare system, but must be available upon request. Competency of nonwaived testing personnel must be assessed at the laboratory where testing is performed (CAP/CLIA number). If there are variations on how a test is performed at different test sites, those variations must be included in the competency assessment specific to the site or laboratory.

Evidence of Compliance:

✓ Records of competency assessment for new and existing testing personnel at the required frequency

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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.*

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

Competency of moderate complexity point-of-care 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 waived testing performed at laboratories with California laboratory licensure, California regulation CCR 17 1036.3 states that a waived laboratory supervisor 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)

GEN.55525 Performance Assessment of Supervisors/Consultants **Phase II**

The performance of section directors/technical supervisors, general supervisors, technical consultants, and clinical consultants is assessed and satisfactory.

NOTE: All responsibilities of section directors/technical supervisors, technical consultants, general supervisors, and clinical consultants must be delegated in writing.

The frequency for assessments must be defined in laboratory policy and be appropriate to the size, test menu, and complexity of the facility. The assessment may take the form of a checklist or other record of performance of responsibilities, as defined by the individual's job description. Unsatisfactory performance must be addressed in a corrective action plan.

If assessment of these individuals is not performed or there are inadequate or inconsistent records, a deficiency should also be cited for DRA.11425 (Director Responsibility - Delegation of Functions) in the Director Assessment Checklist.

If the individuals in these roles are also performing nonwaived testing, competency assessment requirements for testing personnel (GEN.55500) also apply, including all six elements of competency at the required frequencies.

Evidence of Compliance:

- ✓ Job descriptions that list regulatory responsibilities **AND**
- ✓ Records of performance assessment

GEN.57000 Competency Corrective Action **Phase II**

If testing personnel fail to demonstrate satisfactory performance on the competency assessment, the laboratory follows a plan of corrective action to retrain and reassess competency.

NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

Evidence of Compliance:

- ✓ Records of corrective action to include evidence of retraining and reassessment of competency

PHYSICAL FACILITIES

SPACE

Deficiencies in space should be recorded so there is incentive to improve. Deficiencies in space are regarded as minor unless they are so severe as to interfere with the quality of work or quality control activities or safety, in which case they become a Phase II deficiency. As laboratory operations expand over time, Phase I space deficiencies may become Phase II deficiencies by the time of the next inspection.

GEN.59980 Restricted Laboratory Access **Phase I**

The laboratory follows a written policy for restricting access to the laboratory to authorized individuals.

NOTE: This may be accomplished through the use of access codes (security codes, user codes), locks, or other processes (eg, policies and procedures) that limit access to authorized personnel. Access authorization must be maintained and current (eg, inactivated when employment of an authorized individual ends).

The written policy should include:

- *Who is authorized to enter the laboratory on a routine basis (eg, laboratory staff, other employees, etc.) and*
- *How non-laboratory personnel (eg, visitors, vendors, contractors) can obtain access on a temporary basis.*

GEN.60000 Adequate Space **Phase II**

The general laboratory has adequate, conveniently located space so the quality of work, safety of personnel, and patient care/client services are not compromised.

GEN.60100 Adequate Space **Phase I**

All of the following areas have sufficient space and are located so there is no hindrance to the work.

1. **Laboratory director**
2. **Staff pathologists and residents**
3. **Clerical staff**
4. **Section supervisors**
5. **Outpatient/ambulatory waiting and reception**
6. **Lavatories**
7. **Library, conference and meeting room**
8. **Personnel lounge and lockers**

GEN.60150 Adequate Space **Phase I**

There is adequate space for:

1. **Technical (bench) work**
2. **Instruments and equipment**
3. **Storage (records, slides, tissue, etc.)**
4. **Refrigerator/freezer storage**
5. **Media preparation, as applicable**
6. **Accessioning of potentially biohazardous specimens, as applicable**
7. **Radionuclide storage, as applicable**
8. **Microscopy and imaging, as applicable**

ENVIRONMENT

Ambient or room temperature and humidity must be controlled to minimize evaporation of specimens and reagents, to provide proper growth conditions for room temperature incubation of cultures, and not to interfere with the performance of electronic instruments.

GEN.60250 Working Environment **Phase I**

The following are adequate for the facility.

1. **Lighting**
2. **Water taps, sinks, drains**
3. **Electrical outlets**
4. **Ventilation**
5. **Gas and suction, when applicable**

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GEN.61300 Climate Control **Phase II**

The room temperature and humidity are adequately controlled in all seasons.

NOTE: Laboratories must follow manufacturer's instructions for temperature and humidity for proper functioning of instruments, equipment, and test systems.

Evidence of Compliance:

- ✓ Temperature and humidity records, if specific ranges are required for instrument and/or reagent use
- ✓ Records of corrective action when specific ranges are exceeded

GEN.61350 Direct Sunlight **Phase I**

Exposure to direct sunlight is minimized.

NOTE: Direct sunlight should be avoided because of its extreme variability and the need for low light levels necessary to observe various computer consoles, etc. Lighting control should be sectionalized so general levels of illumination can be controlled in areas of the room, if desired.

GEN.61400 Hallway Obstructions **Phase II**

Passageways are unobstructed.

GEN.61500 Environment Maintenance **Phase I**

Floors, walls and ceilings are clean and well-maintained.

GEN.61600 Environment Maintenance **Phase I**

Bench tops, cupboards, drawers and sinks are clean and well-maintained.

COMMUNICATIONS

Communications within the laboratory should be appropriate for the size and scope of the laboratory. Messages should be transferred efficiently to all sections.

GEN.61750 Hand-off Communication **Phase I**

The laboratory follows a defined process for effective "hand-off" communication.

NOTE: The laboratory must have a process for communicating information about pending specimens, tests and patient care issues when responsibility is "handed off" from one person to another, such as at a change in shift, or when the responsibility for a case is transferred from one pathologist to another. The procedure should include provision for asking and responding to questions.

Evidence of Compliance:

- ✓ Logs or message boards showing communication between shifts

GEN.61800 Telephone/Computer Locations **Phase I**

Telephones and computer terminals are conveniently located.

INVENTORY AND STORAGE OF SUPPLIES

GEN.61900 Inventory Control **Phase I**

There is an effective supply inventory control system in operation.

NOTE: An effective inventory control system minimizes emergency requisitions and shortages of supplies.

GEN.62000 Intralaboratory Storage **Phase I**

The intralaboratory storage area is sufficient and free of clutter.

GEN.62020 Centralized Reagent and Supply Storage **Phase II**

If reagents and supplies are stored in a centralized area outside of the laboratory, they are stored and handled in accordance with the manufacturer's instructions, and temperatures are checked and recorded daily using a calibrated thermometer.

NOTE: If the manufacturer defines a required storage temperature range, the temperature of the storage area must be monitored daily. "Daily" means every day (seven days per week, 52 weeks per year). Acceptable ranges must be defined and corrective action must be taken when temperatures fall out of the acceptable range for the specified reagent or supply item.

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, 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. Records must demonstrate the daily functionality of the system.

If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (eg, laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

Evidence of Compliance:

- ✓ Temperature log or records with defined acceptable range including appropriate corrective action

POWER

GEN.66100 Emergency Power **Phase II**

Emergency power is adequate for the functioning of the laboratory.

NOTE: Emergency power supply must be adequate for refrigerators, freezers, incubators, etc., to ensure preservation of patient specimens. Depending on the type of testing performed in the laboratory, emergency power may also be required for the preservation of reagents, the operation of laboratory instruments, and the functioning of the data processing system.

LABORATORY SAFETY

Requirements in this section cover the general safety program for the entire laboratory and must be answered for all laboratory sections. Non-compliance with any of these requirements in any one section of the laboratory represents a deficiency for the entire laboratory. Requirements related to safety features specific to an individual section will be found in the checklist for that section.

With respect to fire safety, if a checklist requirement conflicts with regulations of the Authority Having Jurisdiction (ie, state and local fire codes), the regulations of the Authority Having Jurisdiction take precedence.

SAFETY POLICIES, PROCEDURES, AND RECORDS

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GEN.73200 Safety Policy and Procedure Approval **Phase II**

The laboratory director or designee reviews and approves all new safety policies and procedures as well as changes to existing documents before implementation.

GEN.73300 Safety Policy and Procedure Training **Phase II**

All personnel are trained in safety policies and procedures.

NOTE: Safety training must form a portion of the orientation program for new personnel. Records of the training must be retained. Posting of specific warnings or hazards as appropriate is recommended.

Evidence of Compliance:

✓ Records of personnel review of safety policies and procedures

GEN.73400 Safe Work Practices Review **Phase II**

The laboratory evaluates safe work practices at least annually to identify hazards, investigate problems, and take actions to prevent recurrence or mitigate potential risks, as appropriate.

NOTE: Review must include assessment of work practices for infection control (eg, bloodborne pathogens, highly infectious pathogens), fire prevention and control, electrical safety, chemical safety, radiation safety, personnel and patient security incidents, and environmental safety.

Appropriate risk assessment processes must include the following steps, as applicable:

- *Identifying risks*
- *Planning for prevention and mitigation of safety risks*
- *Implementing risk mitigation plans*
- *Assessing incidents and incorporating those assessments into goals and plans*
- *Evaluating the effectiveness of the plan either annually, or when risks change significantly*
- *Communicating the findings of assessments with the institutional safety committee and/or other stakeholders.*

Evidence of Compliance:

✓ Safety committee minutes for discussion of inspection findings or incident review **OR**

✓ Safety inspection records **OR**

- ✓ Incident report review records and statistics **OR** another method defined by the laboratory director **AND**
- ✓ Records of investigation and action taken for identified problems

GEN.73500 Lab Accidents **Phase II**

The laboratory records and reports all laboratory accidents resulting in property damage or involving spillage of hazardous substances.

GEN.73600 Occupational Injuries and Illnesses **Phase II**

The laboratory reports all occupational injuries or illnesses that require medical treatment (except first aid).

NOTE: For US laboratories subject to OSHA regulations, all workplace fatalities must be reported to the Occupational Safety and Health Administration (OSHA) within eight hours and work-related in-patient hospitalizations, amputations, or losses of an eye within 24 hours.

GEN.73700 Occupational Injury and Illness Evaluation **Phase II**

An evaluation of laboratory accident and occupational injury/illness reports is incorporated into the laboratory's quality management system to avoid recurrence.

Evidence of Compliance:

- ✓ Records of report evaluation **OR** committee minutes with records of discussion

GEN.73800 Emergency Preparedness and Response **Phase II**

The laboratory defines its role and responsibilities in emergency preparedness and response for harmful or destructive events or disasters.

NOTE: The specific elements to be included in the emergency preparedness and response plan must be based on a risk assessment using an "all-hazards" approach to evaluate the types of hazards most likely to occur that would potentially disrupt services. The laboratory's emergency preparedness and response plan must include processes for initiating, managing, and terminating the response, as well as recovery phases.

Written policies and procedures must be developed to support the execution of the laboratory's emergency response plan and the path of workflow, including a communication plan. Laboratories located within a healthcare facility or integrated health system may participate in development of a facility or system-wide emergency preparedness plan rather than an individual laboratory plan, but must ensure that policies and procedures for the plan are clearly defined and address the relevant site-specific risks.

Examples of events that may be addressed in the emergency preparedness plan include situations such as unexpected system failures (eg, HVAC, water, communication, computer system), power failures, natural disasters (eg, tornado, hurricane, earthquake, fire, flood), emerging public health threats (eg, increased numbers of potentially infectious patients or patient specimens), cyber-attacks, terrorist events, or workplace violence.

GEN.73900 Evacuation Plan **Phase II**

The laboratory follows a written comprehensive and workable evacuation plan specific for the laboratory.

NOTE: This plan must cover all personnel, patients and visitors, and must address the special needs of persons with disabilities. Evacuation routes must be clearly marked (Posting evacuation routes is optional). Emergency lighting must be adequate for safe evacuation of the laboratory.

INFECTION PREVENTION AND CONTROL

GEN.74000 Infection Control **Phase II**

The laboratory follows written policies and procedures for infection control that comply with national, federal, state (or provincial), and local guidelines on occupational exposure to bloodborne pathogens and other infectious pathogens, and to the institution's exposure control plan.

NOTE: Universal or standard precautions must be used when handling all blood and potentially infectious materials, such as body fluid specimens and unfixed tissues. The term "universal precautions" refers to a concept of bloodborne disease control requiring all human blood and other potentially infectious materials to be treated as if infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived "low risk" status of a patient or patient population. Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These latter terms define all body fluids and substances as infectious. All personnel must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with blood or other body fluids is anticipated. For laboratories subject to US regulations, policies and procedures must comply with the OSHA Standard on Bloodborne Pathogens. The institution's exposure control plan must address potential hazards that laboratory visitors may encounter.

Evidence of Compliance:

- ✓ Records of universal precaution training for all personnel expected to have contact with infectious materials

GEN.74050 Safe Specimen Handling/Processing **Phase II**

The laboratory safely handles and processes specimens, including those suspected to contain highly infectious pathogens.

NOTE: Suggested topics to be considered in the development of policies and procedures for the safe handling and processing of specimens include the need for tight sealing of containers, avoiding spills of hazardous materials, requirements for wearing gloves, the need for respirator protection, availability and use of vaccinations, and the hazards of sniffing plates.

For specimens suspected of containing highly infectious pathogens, laboratories must review and incorporate national, federal, state (or provincial), and local guidelines for the handling of specimens from patients suspected to have high risk pathogens, such as Francisella tularensis, avian influenza, Ebola, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause disease in individuals and communities.

Evidence of Compliance:

- ✓ Records of universal precaution training for all personnel handling suspected infectious pathogens

GEN.74100 PPE Provision and Usage **Phase II**

Appropriate personal protective equipment (gloves, gowns, masks and eye protectors, etc.) is provided and maintained in a sanitary and reliable condition in all work

areas whenever blood and other potentially infectious materials are handled and in circumstances during which exposure is likely to occur.

NOTE: Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious materials to pass through or reach an individual's work clothes, skin, eyes, mouth, or other mucous membranes under normal conditions of use. In addition to fluid-resistant gowns, aprons may be required if exposure to large volumes of body fluids is anticipated.

OSHA requires unpowdered gloves to be worn with each patient contact and changed after contact when performing vascular access, except when drawing voluntary blood donors. Hands must be cleaned after glove removal using an effective antimicrobial method.

PPE must be made available to laboratory visitors, as applicable.

GEN.74200 PPE Instruction **Phase II**

Personnel are trained on and follow instructions for the proper use of personal protective clothing/equipment (eg, gloves, gowns, masks, eye protectors, footwear).

NOTE: The required elements of training in the use of gloves include:
- *Proper fitting of gloves*
- *Replacing gloves immediately when torn or contaminated*
- *Not washing or disinfecting gloves for reuse*
- *Using hypoallergenic gloves when indicated by patient or health care provider history.*

Evidence of Compliance:
✓ Records of PPE training

GEN.74250 Hand Hygiene **Phase II**

All personnel remove gloves and clean hands using an effective antimicrobial method following contact with blood or other potentially infectious materials or after each patient contact.

GEN.74300 Manual Manipulation of Needles **Phase II**

The facility prohibits the recapping, purposeful bending, breaking, removing from disposable syringes, or other manual manipulations of needles.

NOTE: Resheathing instruments or self-sheathing needles may be used to prevent recapping of needles by hand.

GEN.74400 Prohibited Practices **Phase II**

The facility prohibits smoking, vaping, eating, gum chewing, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas.

GEN.74500 Specimen Transport Procedures **Phase II**

The laboratory receives, handles, and transports specimens (blood and other potentially infectious materials) in appropriately labeled and well-constructed containers with secure lids to prevent leakage during transport.

NOTE: Specimens sent through pneumatic tube systems must be sealed in fluid-tight bags. If pneumatic tube systems are used for transporting specimens, the laboratory must have

procedures to respond to a spill within the tube, including appropriate decontamination measures.

GEN.74600 Spill Handling **Phase II**

The laboratory safely handles spills of blood and other potentially infectious materials.

GEN.74700 Hepatitis B Vaccinations **Phase II**

Personnel reasonably expected to have direct contact with blood and other potentially infectious materials are identified and offered hepatitis B vaccinations free of charge. Personnel that decline the vaccine sign a declination form.

GEN.74800 Viral Exposure **Phase II**

There is a defined process for follow-up after possible and known percutaneous, mucous membrane or abraded skin exposure to HIV, HBV or HCV that includes the following elements.

1. **HIV, HBV and HCV testing of the source patient after consent is obtained**
2. **Appropriate clinical and serologic evaluation of personnel**
3. **Consideration of appropriate prophylaxis for personnel acutely exposed to HIV, HBV or HCV, based upon medical indications, the serologic status and the individual's informed consent**
4. **Reporting of the exposure as required by law**

Evidence of Compliance:

✓ Records of exposure follow-up consistent with policy

GEN.74900 Tuberculosis (TB) Exposure Plan **Phase II**

The tuberculosis exposure control plan includes the following:

- **TB exposure screening at defined intervals for all personnel who may have occupational exposure to tuberculosis**
- **Use of engineering and practice controls for hazardous activities that may potentially aerosolize *Mycobacterium tuberculosis***

NOTE: This requirement does not apply to laboratories that have no patient exposure or do not handle potentially infectious specimens (eg, Mohs or pathology interpretation only).

The plan must define when exposure screening will be performed and who may have occupational exposure to tuberculosis. The CAP recommends that laboratories review the 2019 CDC recommendations (https://www.cdc.gov/tb-healthcare-settings/hcp/screening-testing/) for tuberculosis screening, testing and treatment of US health care personnel published in Morbidity and Mortality Weekly when developing their plan. At minimum, the laboratory must perform exposure screening at the following intervals for personnel who may have occupational exposure:

- *Baseline screening and individual preplacement TB risk assessment*
- *Post exposure screening (known exposure to a person or specimen(s) with potentially infectious TB disease without use of adequate engineering controls and/or personal protection as defined by laboratory policy)*
- *Serial screening, as applicable*
- *As required by state and/or local regulations*

Serial screening (eg, annual) is not indicated for personnel without latent TB infection if there is no known exposure or in settings where there is no evidence of ongoing TB transmission. It

is indicated for personnel at increased occupational risk for TB exposure or in settings where transmission has occurred in the past. Laboratories must consider these risk factors when defining policies for serial testing.

The CDC recommends annual TB education for all personnel, including information about TB exposure risks.

Engineering and work practice controls are required for hazardous activities that potentially may aerosolize Mycobacterium tuberculosis, such as the handling of unfixed tissues in surgical pathology or autopsies, processing specimens in the microbiology section from patients with suspected or confirmed tuberculosis, and handling mycobacterial cultures.

If respiratory protection is needed because of potential exposure to an infectious agent by aerosol or droplet, personnel must use either a properly fit-tested filter respirator (N-95 or higher) or a powered air-purifying respirator (PAPR) equipped with high efficiency particulate air (HEPA) filters. Annual fit testing is required for the use of any tight-fitting respirator.

For laboratories subject to US regulations, the filter respirator must be NIOSH-approved.

GEN.75000 Sterilizing Device Monitoring **Phase II**

All sterilizing devices are monitored periodically with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use.

NOTE: Each sterilizing device must be monitored periodically with a biologic indicator to measure the effectiveness of sterility. Chemical indicators that reflect sporicidal conditions may be used. The test must be performed under conditions that simulate actual use. One recommended method is to wrap the Bacillus stearothermophilus spore indicator strip in packaging identical to that used for a production run, and to include the test package with an actual sterilization procedure. Weekly monitoring is recommended.

Evidence of Compliance:
- ✓ Records of monitoring at defined frequency

FIRE PREVENTION AND PROTECTION

Fire codes are based on a number of variables, such as the type of occupancy, its architecture, and the materials for its construction. The local fire authority is ultimately responsible for fire protection and prevention. Any site-specific arrangements that vary from what is defined in the Fire Prevention and Detection requirements below must be approved by that authority, with records for the approval retained by the laboratory. These records may be presented to an inspector to demonstrate compliance with the variance.

GEN.75100 Fire Prevention Policies and Procedures **Phase II**

Policies and procedures are adequate for fire prevention and control.

NOTE: Fire safety plans must include the use of alarms, response to alarms, isolation of the fire, evacuation of the area, extinguishment of the fire, and the responsibilities of personnel for those elements.

*****REVISED** 08/24/2023***
GEN.75200 Fire Separation **Phase II**

The laboratory is properly separated from inpatient areas and/or provided with automatic fire extinguishing (AFE) systems.

NOTE: For those facilities with no inpatients, no AFE is required.

For those facilities with inpatients, where the laboratory is separated by two-hour construction (rated at 1.5 hours) and Class B self-closing doors (SCD), no AFE system is required unless there are unattended laboratory operations employing flammable or combustible reagents . An AFE system is required for those laboratories separated from inpatient areas by one-hour construction and class C SCD if flammable and combustible liquids are stored in bulk. "Stored in bulk" means more than two gallons (7.5 L) of Class I, II, and IIIA liquids in safety cabinets and safety cans per 100 ft² (9.2 m²), or half that amount if not in safety containers. The following are the definitions of these Classes:

Class I flammable: any liquid that has a closed-cup flash point below 37.8°C and a Reid vapor pressure not exceeding 2068.6 mm Hg at 37.8°C as determined by ASTM D 323

Class II combustible: any liquid that has a flash point at or above 37.8°C and below 60°C

Class IIIA combustible: any liquid that has a flash point at or above 60°C but below 93°C

***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

GEN.75400 Fire Safety Training **Phase II**

New personnel are trained on fire safety, with a fire safety review conducted at least annually.

NOTE: There must be records of fire safety training for all personnel to show that they have been instructed on use and response to fire alarms and to execute duties as outlined in the fire safety plan. While fire exit drills are not required, physical evaluation of the escape routes must be performed annually, to ensure that fire exit corridors and stairwells are clear and that all fire exit doors open properly (ie, not rusted shut, blocked or locked). Paper or computerized testing of an individual's fire safety knowledge on the fire safety plan is acceptable; all personnel must participate at least once a year.

Evidence of Compliance:

- ✓ Records of participation for all personnel in fire safety plan review at least annually (eg, personnel roster with dates of participation)

GEN.75500 Fire Detection/Alarm **Phase II**

There is an automatic fire detection and alarm system.

NOTE: The system must connect to the facility's overall system, where such a system exists. It must sound an immediate alarm in the event of smoke or fire.

The fire alarm must be audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms. Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.

GEN.75600 Fire Alarm Station **Phase II**

There is a fire alarm station in or near the laboratory.

NOTE: Alarm stations must be visible, unobstructed, and accessible.

GEN.75700 Fire Extinguisher Availability **Phase II**

Appropriate portable fire extinguishers are provided for all areas in which flammable and combustible liquids are stored or handled.

NOTE: If gallon bottles of such materials are used, the minimum rating for Class B extinguishers is 10-B or higher. These are best located near or outside of doors leading to the area having solvent fire hazards.

GEN.75800 Fire Extinguisher Personnel Training **Phase II**

If the fire safety plan includes use of fire extinguishers, personnel are instructed in the use of portable fire extinguishers.

NOTE: It is strongly recommended that instruction include actual operation of extinguishers that might be used in the event of a fire, unless prohibited by the local fire authority.

Evidence of Compliance:
- ✓ Records for fire extinguisher training

ELECTRICAL SAFETY

GEN.75900 Electrical Grounding **Phase II**

There are records that all laboratory instruments and appliances are adequately grounded and checked for current leakage before initial use, after repair or modification, and when a problem is suspected.

NOTE: Exceptions to these requirements are as follows:
1. *Devices protected by an approved system of double insulation or its equivalent. Such devices must be distinctively marked*
2. *Devices connected to wall receptacles or circuit breakers with ground-fault circuit interrupter (GCFI) protection built-in need not be checked for current leakage. GCFI interrupters must be utilized in areas where water may pose an added risk.*
3. *Equipment operating at 240 v must be checked for ground integrity only*

Verification of electrical safety is required whenever the electrical/electronic systems of a powered device has been removed or altered. Hospital laboratories may follow ground checks and current leakage checks as performed in patient locations.

In addition, the US Occupational Safety and Health Administration (OSHA) requires that power cords of portable electrical equipment be visually inspected for external defects whenever relocated. Grounding configurations may not be bypassed by, for example, an adapter that interrupts the continuity of the grounding. If manufacturer's recommendations for grounding are available, they must be followed.

CHEMICAL SAFETY

GEN.76000 Chemical Hygiene Plan **Phase II**

The laboratory has a Chemical Hygiene Plan (CHP) that defines the safety policies and procedures for all chemicals used in the laboratory.

NOTE 1: The laboratory director or designee must ensure that the laboratory has a written chemical hygiene plan (CHP) that defines the safety policies for all chemicals used in the laboratory. The plan must include evaluation of carcinogenic potential, reproductive toxicity, and acute toxicity. The plan must include specific handling requirements for all hazardous chemicals used in the laboratory.

The purpose of the CHP is to ensure that the hazards of all chemicals are evaluated, and that information concerning their hazards is transmitted to employers and personnel. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and training of personnel. An acceptable CHP contains the following elements:

1. *Responsibilities of the laboratory director and supervisors*
2. *Designation of a chemical hygiene officer*
3. *Policies for all operations that involve chemicals*
4. *Criteria for the use of personal protective equipment and control devices*
5. *Criteria for exposure monitoring when permissible levels are exceeded*
6. *Provisions for medical consultations and examinations*
7. *Provision for training personnel on the elements of the CHP*
8. *A copy of the OSHA Laboratory Standard, for laboratories subject to US regulations, or (for non-US laboratories) a copy of appropriate local standard*
9. *Evaluation of the carcinogenic potential, reproductive toxicity and acute toxicity for all chemicals used in the laboratory. The product label, safety data sheet (SDS), or for chemicals purchased prior to June 1, 2015 with no appropriate SDS, records of investigation by the safety officer may be used for this evaluation.*
10. *Specific handling requirements for all hazardous chemicals used in the laboratory*

NOTE 2: For laboratories subject to US regulations, chemicals that must be handled as potential carcinogens include those defined by OSHA as "select carcinogens." OSHA defines select carcinogens as any substance that is:

1. *Regulated as a carcinogen by OSHA, has been classified as "known to be carcinogenic" by the NTP, or listed as a group I carcinogen by the IARC*
2. *Has been classified as "reasonably anticipated to be carcinogenic" by the NTP or listed as a group 2A or 2B carcinogen by the IARC if it meets the toxicological criteria listed in the January 31, 1990 Fed Register, pages 3319-3320*

OSHA also requires special containment procedures for substances that are reproductive toxins or are acutely hazardous.

Authoritative sources include (but are not limited to) OSHA (Code of Federal Regulations. Title 29, Part 1910.1200 and 1450); NIOSH (Registry of Toxic Effects of Chemical Substances); the National Toxicology Program; the International Agency for Research on Cancer, and Safety Data Sheets.

Evidence of Compliance:

- ✓ Written evaluation of chemicals used in the laboratory for carcinogenic potential, reproductive toxicity and acute toxicity

GEN.76100 Chemical Safety Document Access **Phase II**

Personnel have access to all of the following documents.

1. **Current Safety Data Sheets (formerly MSDS) and other references that list the details of hazards and the precautions for safe handling and storage**
2. **Chemical Hygiene Plan of the laboratory**
3. **Code of Federal Regulations, Title 29 part 1910.1450 and its appendices (laboratories subject to US regulations only)**

NOTE: It is acceptable for SDS information to be electronically available to personnel, rather than in book format; there is no requirement for paper-based information. Indeed, electronic manuals have the advantage of more accurately reflecting current requirements. The central point is immediate availability to all personnel at all times.

GEN.76200 Chemical Precautionary Labels **Phase II**

Precautionary labels are present on the containers of all hazardous chemicals, indicating type of hazard and what to do if accidental contact occurs.

NOTE: The laboratory may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information otherwise required to be on a label. The written materials shall be readily accessible to the personnel in their work area throughout each work shift. It is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer. Existing labels on incoming containers of hazardous chemicals shall not be removed or defaced, unless the container is immediately marked with the required information.

Additional requirements for the labeling and expiration date of chemicals used for the preanalytic and analytic testing process, such as reagent preparation, are included in the Reagents section of the All Common Checklist. Deficiencies cited relating to the labeling and expiration of chemicals are cited in the checklist section where the chemicals are used.

GEN.76300 PPE And Hazardous Materials **Phase II**

Personnel use the proper personal protective devices when handling corrosive, flammable, biohazardous, and carcinogenic substances.

NOTE: Such devices may include gloves of appropriate composition, aprons, and eye protection. Shoes or shoe covers must protect the entire foot in areas where splashing is expected.

*****REVISED** 08/24/2023***
GEN.76400 Chemical Hazard Emergencies **Phase II**

Explicit instructions are posted, and appropriate supplies available, for the emergency treatment of chemical splashes and injuries and the control of chemical spills wherever major chemical hazards exist.

NOTE: Spill kits must be handled in accordance with manufacturer's instructions. If no expiration date is assigned, the spill kit must indicate the date it was put into service and the laboratory director or designee must assess its usability at least annually.

GEN.76500 Flammable Storage **Phase II**

Supplies of flammable and combustible liquids are reasonable for the laboratory's needs and are properly stored.

NOTE: In each laboratory area:

- *Up to one gallon (3.7 L) of Class I, II and IIIA liquids may be stored outside of fire-resistant cabinets for each 100 ft² (9.2 m²) of space defined by fire-resistant walls/doors*
- *Up to two gallons (7.5 L) of Class I, II, and IIIA liquids may be stored in safety cans and safety cabinets for each 100 ft² (9.2 m²).*

These amounts may be doubled if there is an automatic fire suppression system (eg, sprinklers).

For example, a 1000 ft² (92.9 m²) laboratory defined by fire resistant walls/doors can store:

- *10 gallons (37.8 L) outside a safety cabinet*
- *20 gallons (75.7 L) inside a safety cabinet and cannot exceed 120 gallons (460 L).*

Safety cans should be used for bulk storage of flammable and combustible liquid (National Fire Protection Association classes I and II). Safety cans may be used instead of glass bottles if the purity required does not mandate glass storage. Metal or DOT-approved plastic containers provide an intermediate level of hazard containment between glass and safety cans. One pint (0.4 L) of a highly volatile solvent such as isopentane, stored in glass has about the same ignitability risk as two gallons (7.5 L) stored in safety cans.

Refer to the National Fire Protection Association Standards 45 for more information on guidelines for types of containers that can be used based on volumes of flammable or combustible liquid material stored.

GEN.76600 Volatile Solvent Ventilation **Phase II**

Storage areas and/or rooms where volatile solvents are used are adequately ventilated.

NOTE: Areas where flammable liquids are used must be ventilated for protection of personnel, as well as fire prevention. Areas where flammable liquids are stored should be ventilated primarily for fire protection. Storage cabinets do not need to be vented, but if they are vented the duct system must be explosion proof.

GEN.76700 Acid/Base Storage **Phase II**

Supplies of concentrated acids and bases are stored safely.

NOTE: 1) Storage must be below eye level. Storage near the floor is recommended. 2) Strong acids and bases must not be stored under sinks, where contamination by moisture may occur. 3) Storage containers of acids and bases should be adequately separated to prevent a chemical reaction in the event of an accident/spill/leak. 4) Bottle carriers are used to transport all glass containers larger than 500 mL that contain hazardous chemicals.

*****NEW** 08/24/2023***

GEN.76710 Fume Hood **Phase II**

A properly functioning fume hood (or chemical filtration unit) is available for any procedures using volatile chemicals.

GEN.76720 Formaldehyde and Xylene Safety **Phase II**

Formaldehyde and xylene vapor concentrations are monitored at the required intervals and are maintained below all of the following maxima expressed as parts per million as defined in the table, in all areas of the laboratory where formaldehyde or xylene are used:

	8 hr Time-Weighted Exposure Limit in ppm	Action Level (8 hr Time-Weighted Exposure) in ppm	15 min Short-Term Average Exposure Limit (STEL) in ppm

Formaldehyde	0.75	0.5	2.0
Xylene	100		150

NOTE: Formaldehyde and xylene vapor concentrations must be monitored in all areas where these reagents are used (eg, surgical pathology, frozen section area, histology laboratory, manual/automated coverslipping areas, autopsy room, cytopathology, parasitology).

Initial monitoring for formaldehyde involves the following:
- *Identifying all personnel who may be exposed at or above the action level (8-hr time-weighted exposure) or at or above the short-term exposure limit (STEL) (both must be evaluated) and*
- *Accurately determining the exposure of each individual identified, either through measurement of exposure to each employee or through a representative sampling strategy.*

If a representative sampling strategy is used instead of individual exposure monitoring, the sampling strategy must include measurement of sufficient exposures within each job classification for each work shift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

The results of the formaldehyde monitoring must be made available to personnel (individually in writing or posted in an accessible location) within 15 working days of receipt of results. If results are above the permissible exposure limit, personnel must be provided with a description of the corrective actions being taken to decrease exposure.

Initial formaldehyde monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in ***new or additional*** *exposure to formaldehyde.*

If exposure levels are at or above the action level or STEL, the laboratory must institute engineering controls and work practices to reduce and maintain employee exposures below these limits.

If any personnel report signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the laboratory must promptly monitor the affected individual's exposure.

Additional periodic formaldehyde monitoring is required if personnel are shown by initial monitoring to be exposed at or above the action level or at or above the STEL. This includes:
- *Repeat monitoring of the personnel at least every six months if the results are at or above the action level*
- *Repeat monitoring of the personnel at least once a year under worst conditions if the last monitoring results are at or above the STEL*
- *Periodic monitoring of personnel may be discontinued if results from two consecutive sampling periods taken at least seven days apart show that personnel exposure is below the action level and the STEL*

Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene. Repeat monitoring should be considered when there is a change in production, equipment, process, personnel, or control measures likely to increase exposure levels.

Evidence of Compliance:
- ✓ Records of initial formalin and xylene monitoring and repeat monitoring when indicated **AND**
- ✓ Records of corrective action and timely notifications of personnel when permissible exposure limits are exceeded

COMPRESSED GASES

GEN.76800 Gas Cylinder Storage **Phase II**

Compressed gas cylinders are secured to prevent accidental falling and damage to the valve or regulator.

GEN.76900 Flammable Gas Cylinders **Phase II**

Flammable gas cylinders, if inside a health care facility, are stored properly.

NOTE: Proper storage practices include:
1. *Storage in a separate, ventilated room or enclosure*
2. *Cylinders are positioned well away from open flame or other heat sources, not in corridors and not within exhaust canopies*

RADIATION SAFETY

GEN.77100 Radioactive Material Handling - Specimens **Phase II**

The laboratory safely handles specimens that may contain radioactive material (eg, sentinel lymph nodes, breast biopsies, prostate "seeds", etc.).

NOTE: Policies and procedures may be developed in conjunction with the institutional radiation safety officer, and must comply with state regulations for the safe handling of specimens containing radionuclides. They should distinguish between low radioactivity specimens such as sentinel lymphadenectomy and implant devices with higher radiation levels.

NOTE TO THE INSPECTOR: The following requirements apply to laboratories that use or store radioactive materials.

ENVIRONMENTAL SAFETY

GEN.77200 Ergonomics **Phase II**

There is a written ergonomics program to prevent musculoskeletal disorders (MSDs) in the workplace through prevention and engineering controls.

NOTE: The program may include training of personnel about risk factors, identifying physical work activities or conditions of the job commonly associated with work-related MSDs, and recommendations for eliminating MSD hazards. Laboratory activity, workplace and equipment (eg, chairs, laboratory workstations, computer keyboards, and displays) should be designed to reduce the risks of ergonomic distress disorders and accidents.

Evidence of Compliance:
- ✓ Records of ergonomic evaluation including recommendations for eliminating MSD hazards and appropriate corrective action based on assessment findings

GEN.77300 Excessive Noise **Phase II**

The laboratory protects personnel from excessive noise levels.

NOTE: The laboratory should provide protection against the effects of noise exposure when sound levels equal or exceed an 8-hour time-weighted average sound level of 85 decibels. The

laboratory should monitor noise exposure if there is an indication that excessive noise levels are present (for example, when noise levels exceed 85 decibels, people have to shout to be heard).

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

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 units containing flushing fluid, manufacturer's 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). 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

OTHER HAZARDS

GEN.77500 Liquid Nitrogen and Dry Ice **Phase II**

Adequate policies, procedures, and practices are in place for the use of liquid nitrogen (LN2) and dry ice.

NOTE: Practices for the safe handling of liquid nitrogen and dry ice include:

1. *The mandatory use of appropriate gloves, shielding of all skin, and the use of a face shield or safety goggles when decanting or entering an open container of LN2*
2. *The mandatory use of insulated gloves, dry ice tongs or scoop, and safety goggles/glasses when handling dry ice*
3. *Storage and use of all containers of LN2 and dry ice only in well-ventilated areas. Do not use or store dry ice or LN2 in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. An LN2 or CO2 leak in such an area could cause an oxygen-deficient atmosphere.*
4. *Availability of a Safety Data Sheet*
5. *Training on the safe handling of LN2 and dry ice*
6. *Signage displayed in areas where LN2 is used and/or stored*
7. *Plan for immediate treatment for individuals overcome by toxic or oxygen-displacing fumes*

GEN.77550 Liquid Nitrogen Safety **Phase II**

The laboratory has identified all areas where liquid nitrogen (LN2) is used and/or stored, and there are appropriately mounted oxygen sensors with a low oxygen alarm in all areas where there is an asphyxiation risk.

NOTE: At room temperature liquid nitrogen is converted to nitrogen gas at an expansion ratio of approximately 1:700 (1 L LN2/700 L nitrogen gas). This creates a potential occupational hazard for an oxygen deficient atmosphere. The Occupational Safety and Health Administration (OSHA) states that a hazardous atmosphere may include one where the oxygen concentration is below 19.5% (assuming barometric pressure of 1 atm (sea level)).

The risk of asphyxiation with the use of LN2 is dependent upon the amount and rate of nitrogen gas release, the proximity of personnel, and the ventilation in the area. The laboratory must assess the use of LN2 and determine the risk in the event of a leak or spill of all of the LN2 used in each area and assess the risk of asphyxiation. Functioning oxygen sensors should be in place in all areas where there is a risk of asphyxiation including: confined spaces (eg, cold rooms, closets), poorly ventilated areas, or areas with significant quantities of LN2. For example, on vaporization, one liter of LN2 will fill 24.6 cu ft of space. Use of small volumes of LN2 (eg, ≤1 liter) by trained personnel in well-ventilated areas may not require oxygen sensors. The assessment and the determination that these areas do not require oxygen sensors must be recorded by the laboratory.

Appropriate placement of oxygen sensors is at typical breathing height while working (seated, standing, bending down) close to where liquid nitrogen is used and where a leak would most likely occur. An audible low oxygen alarm must be installed along with the oxygen sensor to alert persons in the area of a hazardous condition. Laboratories may determine if visual alarms are also appropriate for their facility.

Oxygen monitoring devices need to be maintained and calibrated following manufacturer instructions. Device display/readout should be visually checked following a defined schedule to ensure proper operation.

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GEN.77600 UV Light Exposure **Phase II**

The laboratory follows written policies and procedures to prevent or reduce ultraviolet light exposure from instrument sources.

NOTE: UV light may cause corneal or skin burns from direct or deflected light sources. Wherever UV light sources are used (eg, in biological safety cabinets, cryostats, or for gel visualization), suitable and adequate personal protective equipment must be provided, and appropriate approved signage displayed. Laboratories may obtain information on safety from manufacturers of devices that emit UV light.

A suggested sign for display is: Warning: This device produces potentially harmful ultraviolet (UV) light. Protect eyes and skin from exposure.

Evidence of Compliance:

- ✓ Warning signage on source equipment **AND**
- ✓ Suitable PPE available, as required

GEN.77700 Latex Allergy **Phase II**

The laboratory has processes to protect personnel and patients from allergic reactions from exposures to natural rubber latex in gloves and other products.

NOTE: The latex program should address at least the following elements:

1. *Selection of products and implementation of work practices that reduce the risk of allergic reactions. If latex gloves are used, the employer should provide reduced protein, powder-free gloves to protect personnel from infectious materials*
2. *Provision of education programs and training materials about latex allergy*
3. *Evaluation of current prevention and control strategies for personnel whenever there is a new latex allergy diagnosis*

Evidence of Compliance:

- ✓ Records of personnel education/training on latex allergies **AND**
- ✓ Records of evaluation of the plan, when appropriate

WASTE DISPOSAL

GEN.77800 Hazardous Chemical Waste Disposal **Phase II**

Written policies and procedures are adequate for hazardous chemical waste disposal.

NOTE: The laboratory is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition. The method for the disposal of all solid and liquid wastes is in compliance with national, federal, state (or provincial), and local laws and regulations. Whether or not laboratory management is responsible for waste disposal, the laboratory should have documentation that the facility is in compliance with all applicable regulations. Prevailing local, state and federal (EPA) regulations should be reviewed by the laboratory director, safety officer or hospital engineer to ensure that the laboratory is in compliance with regulations.

Evidence of Compliance:

- ✓ Records of review of regulations for compliance

GEN.77825 Hazardous Waste Registration and Regulations **Phase II**

Laboratories that generate hazardous wastes are registered with the Environmental Protection Agency (EPA) and/or appropriate national, federal, state (or provincial), and local governmental agencies, as applicable, and comply with applicable regulations based on the amount of wastes generated.

NOTE: For laboratories subject to US regulations, requirements for registration and record keeping vary based on the amounts of hazardous waste generated and by the state in which the laboratory is located. Laboratories that are categorized as "very small quantity" generators do not require registration in most states. "Small quantity" generators and "large quantity" generators are usually required to register with the EPA, even if the laboratory contracts with a service for waste disposal. Information on defining hazardous wastes, waste generator categories, and variations between states can be found at www.epa.gov. Links to hazardous waste programs and specific state agencies can be found at https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies.

Laboratories that are part of a larger facility that generates hazardous waste may register with the facility and maintain facility records.

Laboratories that are not subject to US regulations must follow applicable national, state or provincial, and local laws and regulations for hazardous wastes.

Evidence of Compliance:

- ✓ EPA registration, if applicable **AND**
- ✓ Records of hazardous waste management, if applicable

GEN.77900 Biohazard Disposal Containers **Phase II**

All infectious wastes (eg, glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded into "biohazard"-labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal.

NOTE: All infectious wastes must be incinerated or appropriately decontaminated before being sent to a sanitary landfill. Stool and urine waste may be discarded into the sanitary sewerage system.

GEN.78000 Sharps Disposal **Phase II**

Sterile syringes, needles, lancets, or other blood-letting devices ("sharps") that are capable of transmitting infection are used once only, and all waste sharps are discarded in puncture-resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.

NOTE: Shearing or breaking of contaminated sharps is prohibited. Bending, recapping, or removing contaminated needles is prohibited as a general practice. Needles are expected to be used and immediately discarded, un-recapped, into accessible sharps containers.