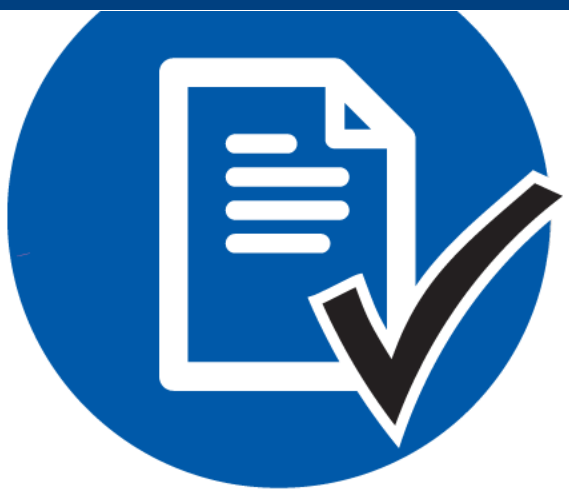
COLLEGE of AMERICAN PATHOLOGISTS

Master

Laboratory General Checklist

CAP Accreditation Program



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Laboratory General Checklist

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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-*LAB* Solutions. 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.

SUMMARY OF CHECKLIST EDITION CHANGES
Laboratory General Checklist
08/21/2017 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 listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements

Requirement	Effective Date
GEN.20450	08/17/2016
GEN.40495	08/21/2017
GEN.40502	08/21/2017
GEN.40503	08/21/2017
GEN.40504	08/21/2017
GEN.40506	08/21/2017
GEN.40507	08/21/2017
GEN.40509	08/21/2017
GEN.50630	08/17/2016
GEN.54025	08/17/2016
GEN.55499	08/21/2017
GEN.55510	08/21/2017
GEN.62020	08/21/2017
GEN.74250	08/17/2016
GEN.77115	08/21/2017
GEN.77120	08/21/2017

GEN.77125	08/21/2017
GEN.77130	08/21/2017
GEN.77135	08/21/2017
GEN.77140	08/21/2017
GEN.77145	08/21/2017
GEN.77150	08/21/2017
GEN.77155	08/21/2017
GEN.78200	08/21/2017
GEN.78225	08/21/2017
GEN.78250	08/21/2017
GEN.78275	08/21/2017
GEN.78300	08/21/2017
GEN.78325	08/21/2017
GEN.78350	08/21/2017
GEN.78375	08/21/2017
GEN.78400	08/21/2017
GEN.78425	08/21/2017
GEN.80000	08/17/2016
GEN.80100	08/17/2016
GEN.80200	08/17/2016
GEN.80300	08/17/2016
GEN.80400	08/17/2016
GEN.80500	08/17/2016
GEN.80700	08/17/2016
GEN.81325	08/17/2016
GEN.81910	08/21/2017
GEN.83510	08/21/2017
GEN.88040	08/17/2016

REVISED Checklist Requirements

Requirement	Effective Date
GEN.20316	08/17/2016
GEN.20330	08/21/2017
GEN.20377	08/21/2017
GEN.23584	08/21/2017
GEN.40100	08/21/2017
GEN.40490	08/17/2016
GEN.40491	08/17/2016
GEN.40497	08/21/2017
GEN.40498	08/21/2017
GEN.40942	08/21/2017
GEN.41042	08/17/2016
GEN.41306	08/17/2016
GEN.41310	08/17/2016
GEN.41350	08/17/2016
GEN.41460	08/21/2017
GEN.41485	08/21/2017
GEN.43022	08/21/2017
GEN.43150	08/21/2017
GEN.43200	08/21/2017
GEN.43325	08/21/2017
GEN.48500	08/21/2017
GEN.50057	08/17/2016
GEN.50614	08/17/2016
GEN.51728	08/17/2016
GEN.52842	08/21/2017

GEN.52900	08/17/2016
GEN.53400	08/17/2016
GEN.53600	08/21/2017
GEN.53625	08/21/2017
GEN.53650	08/21/2017
GEN.54000	08/17/2016
GEN.54400	08/21/2017
GEN.54750	08/21/2017
GEN.55450	08/21/2017
GEN.55500	08/21/2017
GEN.55525	08/21/2017
GEN.73800	08/21/2017
GEN.74000	08/21/2017
GEN.74100	08/21/2017
GEN.74200	08/17/2016
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GEN.77400	08/21/2017
GEN.81500	08/21/2017
GEN.81900	08/21/2017
GEN.82000	08/21/2017
GEN.82100	08/17/2016
GEN.82900	08/17/2016
GEN.83000	08/17/2016
GEN.83600	08/21/2017
GEN.86130	08/21/2017
GEN.86200	08/21/2017
GEN.86400	08/21/2017
GEN.86500	08/21/2017
GEN.86600	08/17/2016
GEN.87020	08/17/2016

DELETED/MOVED/MERGED Checklist Requirements

Requirement	Effective Date
GEN.30070	08/16/2016
GEN.85000	08/16/2016

UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

All checklist requirements contain a requirement number, subject header, phase, and a declarative statement. Some requirements also contain a NOTE and/or Evidence of Compliance.

The NOTE portion of a checklist requirement provides additional detail to assist in interpreting the requirement.

Evidence of Compliance (EOC) is intended to:

- Suggest specific examples of acceptable records; some elements are required
- Assist in inspection preparation and for managing ongoing compliance
- Drive consistent understanding of requirements

If a policy or procedure is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies or procedures covered in the CAP checklists must be a written document. A separate policy or procedure may not be needed for items in EOC if it is already addressed by an overarching policy.

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. For suggestions on how inspectors can assist the Laboratory General inspector, please refer to the Laboratory General (GEN) section in the Laboratory Accreditation Manual.

Note for non-US laboratories: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist.

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 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 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

Biennial - Every 24 calendar months

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

Calibrator, historical - The set of archived results of a single-point calibrator that demonstrates stability of the assay over time

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

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 (i.e. matrix effects are absent).

Confirmation - Substantiation of the correctness of a value or process

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

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

Correlation - Establishment of agreement 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 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

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.

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, regional, or local authority having jurisdiction over *in vitro* diagnostic test systems.

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

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

Instrument - An analytical unit that uses samples to perform chemical or physical assays (e.g. 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

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

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

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 (e.g. replacement of critical components)

Personnel - The collective group of employees and contractors employed in the laboratory organization. Contractors may include those individuals contracted by the laboratory, such as pathologists, medical technologists, 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 - 1) Set of basic principles or guidelines that direct or restrict the facility's plans, actions, and decisions; 2) Statement that tells what should or should not be done

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 - 1) Specified way to carry out an activity of a process (also referred to by ISO as "work instructions"; 2) Set of steps performed that tells "how to do it" to achieve a specified outcome, including decisions to be made

Process - 1) Set of interrelated or interacting activities that transforms inputs into outputs; 2) Series of events, stages, or phases that takes place over time that tells "what happens" or "how it works"

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.

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

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

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.

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

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

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

The laboratory must have a written quality management program to systematically ensure the quality of laboratory services. In laboratories that are part of a larger institution (e.g. a hospital), the laboratory quality management program must be integrated with the institutional program.

Although effective organization of the laboratory and appropriate delegation of duties are part of quality management, these areas are addressed in the Director Assessment Checklist. Quality management requirements pertaining to all laboratory sections are addressed in the All Common Checklist.

Inspector Instructions:

	• Policy for communication of employee concerns • Sampling of quality indicators with follow-up actions when targets are not achieved • Annual appraisal of effectiveness of the QM Program • Document control policy • Record/specimen retention policy • Error, complaint, and incident logs with corrective/preventative actions • Device-related adverse patient event procedure and records of reporting (if applicable) • Results of the laboratory's self-inspection and correction of deficiencies • Sampling of records of manufacturer's recalls and records of follow-up
	• CAP sign regarding the reporting of quality concerns
	• How is the laboratory's QM performance communicated to other hospital departments? • How was referring physician, client, or patient satisfaction measured? What were the results and what actions were taken as a result of the findings? • Is there a specific example when problems were identified that could have interfered with patient care or safety?
	• If any problems are found during review of quality measurements or when asking questions, further evaluate the laboratory's investigation and resolution, including root cause analysis and associated risk-reduction activities when applicable • If trends in negative feedback are identified in the satisfaction survey, further evaluate investigation and corrective actions • Review interim CAP self-inspection records to determine if a thorough self-inspection, with timely correction of deficiencies, was performed. Investigate if deficiencies identified in the current inspection were non-compliant at the time of the self-inspection. Notify the inspection team leader if the review of the self-inspection records reveals concerns about the quality of the evaluation or the correction of deficiencies

GEN.13806 QM Program **Phase II**

The laboratory has a written quality management (QM) program.

NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program. The QM plan may be based upon some reference resource such as CLSI QMS01-04; the ISO 9000 series or ISO 15189; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design. If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM plan.

REFERENCES
1) Joint Commission on Accreditation of Healthcare Organizations. Using Performance Improvement Tools in Health Care Settings, Third Edition. Oakbrook Terrace, IL: JCAHO, 2006
2) ISO Standards compendium: ISO 9001:2000, Quality management systems -- Requirements. Geneva, Switzerland: International Organization for Standardization, 2000
3) ISO 15189:2003 Medical laboratories -- Particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2003
4) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition. CLSI document QMS01-A4 (ISBN 1-56238-761-8 [Print]; ISBN 1-56238-762-6 [Electronic]). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2011.
5) Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Chicago, IL: CAP Press, 2005
6) Valenstein P. Quality Management In Clinical Laboratories. Chicago, IL: CAP Press, 2005
7) Berte L. Quality Manual Preparation Workbook for Blood Banking, 2nd edition. Bethesda, MD: AABB Press, 2005

GEN.16902 QM Implementation **Phase II**

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.

NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.

Evidence of Compliance:

✓ Evidence that the plan has been implemented as designed requires all of the following:
- quality measurements/assessments specified in the plan are being substantially carried out;
- there is evidence of active review of quality measurements;
- if target performance levels are specified in the plan and the targets are not being met, there are records of follow-up action;
- any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay recorded; **AND**
- any communication of information that is required by the plan have taken place

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1249]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1299]

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

The QM program covers all areas of the laboratory and all beneficiaries of service.

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

GEN.20208 QM Patient Care Services **Phase II**

The QM program includes a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services.

NOTE: There must be an organized process for recording of 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 or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must record investigation and resolution of these problems. Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including "near misses" and sentinel events). Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1233]
2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003 (4.8)
3) College of American Pathologists. CAP Quality Management Education Resources. Root Cause Analysis [online course]. 2010.
4) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1249]
5) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1299]
6) Clinical and Laboratory Standards Institute. *Nonconforming Event Management,* 2nd ed. CLSI guideline QMS11-ED2. Clinical and Laboratory Standards Institute, Wayne, PA; 2015.

*****REVISED** 08/17/2016***

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

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

NOTE: Key indicators should monitor activities critical to patient outcome or that may affect many patients. The laboratory must evaluate its indicators by comparing its performance against available benchmarks. The laboratory should also evaluate the effectiveness of each corrective action. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories should monitor multiple aspects of the testing process appropriate to their scope of service.

For laboratories that have implemented one or more individualized quality control plans (IQCPs), the quality management program must include a review of the ongoing monitoring of the effectiveness of each IQCP.

While there is no requirement to monitor any specific laboratory indicator, the following key quality indicators have been commonly used to measure laboratory performance in a consistent manner and are important to clinicians and patients as indices of care.

1. *Patient/Specimen Identification: Percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors*
2. *Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer*
3. *Specimen Acceptability: Percent of specimens accepted for testing*
4. *Stat Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority (e.g. emergency department or intensive care unit specimens), mean or median turnaround time, or the percent of specimens with turnaround time that falls within an established limit*
5. *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*

6. *Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents*
7. *Corrected Reports – General Laboratory: Percent of reports that are amended*
8. *Amended Reports – Anatomic Pathology: Percent of reports that are amended*
9. *Surgical Pathology/Cytology Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type*
10. *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*
11. *Blood Culture Contamination: Percent of blood cultures that grow bacteria that are highly likely to represent contaminants*

Performance of indicators should be compared with benchmarks, preferably from multi-institutional studies conducted within ten years of the laboratory's use of the monitor, where such surveys are available.

Both the College of American Pathologist's Q-TRACKS Program itself and publications of Q-TRACKS studies in the Archives of Pathology provide information regarding definitions of quality indicators and demonstrate statistically valid peer-group performance standards.

For benchmark information on commonly used quality indicators, please refer to the Quality Management Quality Indicator Monitoring Guidance Document posted on the CAP Website at the following link: http://www.cap.org/apps/docs/laboratory_accreditation/qim.pdf

Evidence of Compliance:

- ✓ Listing of quality indicators that include the following:
  - indicators for pre-analytic, analytic, and post-analytic phases **AND**
  - indicators to address the scope of testing and laboratory services **AND**
  - frequency for monitoring each indicator **AND**
  - defined benchmarks for the performance of each indicator **AND**
- ✓ Quality management data and reports for quality indicator monitoring and evaluation, including comparison against benchmark data, and corrective action when targets are not met

REFERENCES

1) http://www.cap.org/apps/docs/laboratory_accreditation/qim.pdf
2) Clinical Laboratory Improvement Amendments 42 CFR § 493.1701
3) Howanitz PJ, *et al*. Continuous wristband monitoring over 2 years decreases identification errors: a College of American Pathologists Q-TRACKS Study. *Arch Pathol Lab Med*. 2002; 126:809-815
4) Valenstein PN, Walsh MK, Stankovic AK. Accuracy of send-out test ordering: a College of American Pathologists Q-Probes study of ordering accuracy in 97 clinical laboratories. *Arch Pathol Lab Med*. 2008;132:206-210
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8) Nakhleh RE, Souers R, Ruby SG. Physician satisfaction with surgical pathology reports: a 2-year College of American Pathologists Q-TRACKS study. *Arch Pathol Lab Med*. 2008;132:1719-1722
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10) Bruce A. Jones MD, Molly K. Walsh PhD and Stephen G. Ruby MD. 2006: Hospital nursing satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 162 institutions. *Arch Pathol Lab Med*. 2006;130:1756-1761
11) Raab S, Nakhleh RE, Ruby SG. Patient safety in anatomic pathology: measuring discrepancy frequencies and causes. *Arch Pathol Lab Med*. 2005;129:459-466
12) Nakhleh RE, Idowu MO, Souers RJ, Meier FA, Bekeris LG. Mislabeling cases, specimens, blocks, and slides; a College of American Pathologists study of 136 institutions. *Arch Pathol Lab Med.* 2011;135(8):969-97
13) Novis DA, *et al.* Quality indicators of fresh frozen plasma and platelet utilization. *Arch Pathol Lab Med*. 2002; 126:527-532
14) Bekeris LG, Tworek JA, Walsh MK, Valenstein PN. Trends in blood culture contamination: a College of American Pathologists Q-TRACKS study of 365 institutions. Arch Pathol Lab Med. 2005;129:1222-1225
15) Zarbo RJ, Jones BA, Friedberg RC, Valenstein PN, Renner SW, Schifman RB, Walsh MK, Howanitz PJ. Q-TRACKS: A College of American Pathologists Program of Continuous Laboratory Monitoring and Longitudinal Performance Tracking. Arch Pathol Lab Med. 2002;126:1036-1044
16) Raab SS, Jones BA, Souers R, Tworek JA. The effect of continuous monitoring of cytologic-histologic correlation data on cervical cancer screening performance. Arch Pathol Lab Med. 2008;132:16-22
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18) Bonini P, *et al.* Errors in laboratory medicine. *Clin Chem.* 2002, 48:691-698
19) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1249]

20) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1299]
21) Clinical and Laboratory Standards Institute. *Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline.* CLSI guideline QMS12-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2010.

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

The laboratory has a procedure for employees and patients to communicate concerns about quality and safety to management.

NOTE: The investigation and analysis of employee and patient complaints and suggestions, with corrective or preventive action as appropriate, should be a part of the laboratory quality management program and be specifically addressed in laboratory quality management records.

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

*****REVISED** 08/21/2017***
GEN.20330 CAP Sign **Phase II**

The laboratory prominently posts the official CAP sign regarding the reporting of quality concerns to the CAP.

NOTE: Laboratories that have applied to the CAP for accreditation that are not yet accredited must post the sign provided with the CAP application materials. Once a laboratory is accredited, the laboratory receives the official sign for posting.

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 an employee in response to a complaint or concern made to the CAP or other regulatory organization regarding laboratory quality or safety.

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.

GEN.20335 Customer Satisfaction **Phase I**

The laboratory has measured the satisfaction of healthcare providers or patients with laboratory services within the past two years.

NOTE: Satisfaction metrics are important for understanding the needs of clients (physicians, patients, referring laboratories, nurses, etc.) to improve laboratory services. Experience has shown that surveys are more informative if they are conducted anonymously and allow for open ended comments. The sample size should be adequate. A numeric satisfaction scale allows for calculation of statistics.

Evidence of Compliance:
✓ Records of the design and results of satisfaction surveys

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

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7) Nakhleh RE, Souers R, Ruby SG. Physician satisfaction with surgical pathology reports: a 2-year College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2008; 132:1719-1722.
8) Jones BA, Bekeris LG, Nakhleh RE, *et al*. Physician satisfaction with clinical laboratory services: a College of American Pathologists Q-Probes study of 138 institutions. *Arch Pathol Lab Med.* 2009; 133:38-43.

GEN.20340 Notifications From Vendors — Phase II

The laboratory manages notifications from vendors of defects or issues with supplies or software that may affect patient care.

NOTE: Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory should take action on those that have the potential to affect testing results or laboratory services.

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

GEN.20351 Adverse Patient Event Reporting — Phase II

The laboratory has a procedure for reporting 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 days from the time medical personnel become aware of the 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 (e.g. limitations of sensitivity, specificity, accuracy, and precision) is not reportable.*

The laboratory should have written procedures for 1) the identification and evaluation of adverse patient events, 2) the timely submission of MDR (medical device reporting) reports, and 3) 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 (e.g. hospital laboratories).

The laboratory should educate its personnel in the FDA MDR requirements.

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 Federal/State/Local Regulations **Phase I**

The laboratory has a policy for ensuring compliance with applicable federal, state and local laws and regulations.

NOTE: Applicable federal, state and local requirements may include but are not limited to the following areas: handling radioactive materials, shipping infectious or diagnostic materials, reporting infectious disease testing results, personnel qualifications, retention of specimens and records, hazardous waste disposal, 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, and donation of blood. The checklists contain specific requirements on these areas.

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1): [42CFR493.1101(c)]

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 and summary charts), and forms are in use and that records for approval, review, and discontinuance are available.

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.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.
2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003
3) Clinical and Laboratory Standards Institute. *Laboratory Personnel Management, 1st ed.* CLSI guideline QMS16-ED1. Clinical and Laboratory Standards Institute, Wayne, PA; 2015.

*****REVISED** 08/21/2017***
GEN.20377 Record/Specimen Retention **Phase II**

Laboratory records and materials are retained for an appropriate time.

NOTE: Policies for retention of records and materials must comply with federal, state, and local laws and regulations and with the retention periods listed 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, Cytopathology, Cytogenetics, Molecular Pathology, Reproductive Laboratory Medicine, and Transfusion Medicine Checklists.

Type of Record/Material	Retention Period

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
Validation/verification of method performance specifications	2 years after discontinuation of the test
Proficiency testing records	2 years (5 years for transfusion medicine)
Policies and procedures	At least 2 years following discontinuance (5 years for transfusion medicine)
Quality control records	2 years (5 years for transfusion medicine)
Individualized Quality Control Plan (IQCP), including risk assessment and supporting data, and approval of quality control plan Ongoing quality assessment data	2 years following discontinuation of the IQCP 2 years
Instrument maintenance* and function check records	2 years
Chain-of-custody collection, receipt, accessioning, and handling records	2 years (or longer as applicable)
Personnel Records Competency assessment records Training records	 2 years (5 years for transfusion medicine) 2 years (5 years for transfusion medicine)
Patient Specimens (stored under appropriate conditions) Serum, heparinized plasma, EDTA plasma, CSF, and body fluids (except urine) Whole blood specimens, including blood gas specimens Urine	 48 hours Not defined 24 hours; exceptions may be made at the discretion of the laboratory director.
Clinical Pathology Slides Blood Films Permanently stained body fluid slides	7 days

Permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles)	
Testing Records Instrument printouts and worksheets ** Patient test results and reports, including original and corrected reports, and referral laboratory reports Direct-to-consumer testing results, including reference intervals	 2 years 10 years
Laboratory Computer Services Computer system validation records Records of changes to software, the test library, and major functions of laboratory information systems Ongoing computer system checks (e.g. calculation verification)	 2 years beyond the life of the system 2 years

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

*** 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., so long as the computer retains the data for at least two years. Manual computer entry of patient result data from worksheets, print-outs, 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.*

Evidence of Compliance:

✓ Written policy for retention of records, specimens, and slides

REFERENCES

1) College of American Pathologists. Guidelines for the retention of laboratory records and materials. Northfield, IL: CAP, current edition
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1105]
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1283(b)]

GEN.20425 Record Retention **Phase II**

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2005(Oct 1):1033 [42CFR493.1105(b)]

*****NEW** 08/17/2016***

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

The laboratory follows a written policy for the management and correction of laboratory records, including quality control data, temperature logs, and intermediate test results or worksheets.

NOTE: Laboratory records and changes to such records must be legible and indelible. Original (erroneous) entries must be visible (i.e. erasures, white and correction fluid are unacceptable) or accessible (e.g. 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 following the policy

*****REVISED** 08/21/2017***

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

The laboratory has conducted a thorough interim self-inspection and has corrected 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. It is an important aspect of continuing education, laboratory improvement, and continuous compliance. Laboratories must retain records of the CAP self-inspection, as well as the corrective action for deficiencies, as part of the quality management program. 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

REFERENCES

1) Clinical and Laboratory Standards Institute. *Assessments: Laboratory Internal Audit Program; Approved Guideline.* CLSI document QMS15-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2013.

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

The laboratory has a policy that addresses compliance with the CAP terms of accreditation.

NOTE: The CAP terms of accreditation are listed in the laboratory's official notification of accreditation. The policy must include notification of CAP regarding the following:

1. *Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than two working days after the laboratory learns of an investigation or adverse media attention. For laboratories subject to US regulations, this notification must include any complaint investigations conducted or warning letters issued by any oversight agency (e.g. CMS, State Department of Health, The Joint Commission, FDA, OSHA).*
2. *A facility must notify the CAP as soon as it finds itself to be the subject of a validation inspection*
3. *Discovery of actions by laboratory personnel that violate national, state or local regulations*
4. *Change in laboratory test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing*
5. *Change in laboratory directorship, location, ownership, name, insolvency, or bankruptcy; notification must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than two working days afterwards.*

Laboratories subject to US regulations must also notify the US Department of Health and Human Services.

In addition, the policy must address:

6. *Provision of a trained inspection team comparable in size and scope if requested by CAP at least once every two-year accreditation period*
7. *Cooperation with CAP and HHS when the laboratory is subject to a CAP or HHS complaint investigation or validation inspection*
8. *Adherence to the Terms of Use for the CAP Certification Mark of accreditation*
9. *For laboratories subject to US regulations, availability, on a reasonable basis of the laboratory's annual proficiency testing results upon request of any person*

Evidence of Compliance:

✓ Records of notification, if applicable

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

There is a written quality control program that 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 (1) number and frequency of controls; (2) establishment of tolerance limits for control testing; and (3) corrective actions based on quality control data. Quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director, supervisor or laboratory quality control coordinator).

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.

Inspector Instructions:

DISCOVER

- Follow a patient specimen beginning with test ordering through patient identification, phlebotomy/collection, labeling, transport, receipt and processing, delivery to test area, analysis, result review, and reporting. Determine if practice matches related policies and procedures.

SPECIMEN COLLECTION INSTRUCTIONS

Inspector Instructions:

	• Sampling of specimen collection policies and procedures • Specimen handling policies and procedures for referral of testing
	• Specimen collection manuals (available)

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.

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.

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

The specimen collection manual is distributed to all specimen-collecting areas within the hospital (nursing stations, operating room, emergency room, out-patient areas) AND to areas outside the main laboratory (such as physicians' offices or other laboratories).

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(d)]

***REVISED** 08/21/2017*

GEN.40100 Specimen Collection Manual Elements **Phase II**

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

1. **Preparation of the patient**
2. **Type of collection container and amount of specimen to be collected**
3. **Need for special timing for collection (*e.g.* creatinine clearance)**
4. **Types and amounts of preservatives or anticoagulants**
5. **Need for special handling between time of collection and time received by the laboratory (*e.g.* refrigeration, immediate delivery)**
6. **Proper specimen labeling**

7. Need for appropriate clinical data, when indicated

NOTE: Because of the importance of clinical information in the practice of surgical pathology and cytopathology, requisitions for such specimens should include pertinent clinical data, as well as pre-operative and/or post-operative diagnosis. Written instructions should be available for 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. A variety of tests in clinical pathology also require specific clinical information (e.g. maternal AFP screening, TDM peak and trough measurements, and antibiotic therapy) or special instructions for collection, preservation, and storage (e.g. 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.

REFERENCES

1) Nakhleh RE, *et al*. Necessity of clinical information in surgical pathology. A College of American Pathologists Q-Probes study of 771 475 surgical pathology cases from 341 institutions. *Arch Pathol Lab Med.* 1999;123:615-619
2) Burton JL, Stephenson TJ. Are clinicians failing to supply adequate information when requesting a histopathological investigation? *J Clin Pathol*. 2001;54:806-808
3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Fed Register.* 2003(Jan 24):3706 [42CFR493.1251(b)(1)]
4) Clinical and Laboratory Standards Institute. *Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline*; 3rd ed. CLSI document GP15-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2008.
5) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(a)]
6) Clinical and Laboratory Standards Institute. *Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline.* CLSI document C62-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

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, transport time, and the interval before separation of blood cells from serum/plasma. For coagulation tests, important considerations include proper filling of the collection tube, the use of waste tubes, and, if blood must be drawn through an indwelling line, flushing of the line. For surgical pathology and cytopathology, specimens must be preserved by proper fixation or refrigeration. Twenty-four-hour urine specimens may require special preservatives for specific tests. Also, it may be necessary to collect specific patient information required by the testing laboratory (e.g. menstrual history for cytopathology, gestational age for prenatal neural tube defect screening, preoperative diagnosis for surgical pathology, and bleeding history for specialized coagulation assays).

For microbiology specimens, guidelines for the timing of specimen collection, collection techniques, and selection of appropriate collection devices and transport media must be followed as stipulated by the referral laboratory.

For newborn screening specimens, the specimen collection, application and drying of blood spots, and submission of specimens to the referral laboratory must follow the designated newborn screening laboratory's instructions and be in compliance with the most recent edition of the CLSI Document NBS01 and state or local regulations. Specimens should 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.

Evidence of Compliance:

✓ Written procedure for submission of specimens to referral laboratories, consistent with the referral laboratory collection and handling requirements

REFERENCES

1) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150
2) Narayanan S. The preanalytic phase. An important component of laboratory medicine. *Am J Clin Pathol.* 2000;113:429-452
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(a)]
4) Clinical and Laboratory Standards Institute (CLSI). *Blood Collection on Filter Paper for Newborn Screening Programs*. CLSI Standard NBS01-A6. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA

SPECIMEN COLLECTION AND LABELING

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

Inspector Instructions:

READ	• Specimen collection (patient identification, specimen labeling, correction of labeling, and adverse event) policies and procedures • Sampling of phlebotomy/clinical specimen collection training records • Paternity/forensic collection policies and procedures
OBSERVE	• Sampling of phlebotomy supplies, collection devices, transport media (expiration date, storage) • Specimen collection at one or more sites within the institution.
ASK	• How is feedback related to specimen quality provided to the individuals collecting patient specimens, including non-laboratory staff, as applicable?
DISCOVER	• If specimen collection errors are a recurring problem, further evaluate the laboratory's investigation of how the errors occurred and the corrective actions that were implemented

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

Specimen collection supplies such as blood collection tubes and collection devices (e.g. 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.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Blood Collection on Filter Paper for Newborn Screening Programs*. CLSI Standard NBS01-A6. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA

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

There are records that all personnel collecting patient specimens have been trained in collection techniques and in 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. All types of specimen collection techniques (e.g. 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. If the laboratory uses prepackaged kits for specimen collection, any special instructions that accompany the kit must be part of the training.

REFERENCES
1) Galena HJ. Complications occurring from diagnostic venipuncture. *J Fam Pract.* 1992;34:582-584
2) Piton JD, Forstater AT. Recurrent asystole associated with vasovagal reaction during venipuncture. *J Emerg Med.* 1993;11:723-727
3) Becan-McBride K, *et al*. Phlebotomy. Collection, professionalism, and QA. Chicago, IL: ASCP Press, 1993
4) Strand CL, *et al*. Effect of iodophor versus iodine skin preparation on blood culture contamination rate. *JAMA.* 1993;269:1004-1006
5) Spitalnic SJ, *et al*. The significance of changing needles when inoculating blood cultures; a meta-analysis. *Clin Infect Dis.* 1995;21:1103-1106
6) Strasinger SK, di Lorenzo MA. Phlebotomy workbook for the multiskilled healthcare professional. Philadelphia: FA Davis, 1996
7) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy. 12th edition. Northfield, IL: College of American Pathologists, 2007
8) Gibb AP, *et al*. Reduction in blood culture contamination rate by feedback to phlebotomists. *Arch Pathol Lab Med.* 1997;121:50-507
9) Klosinki DD. Collecting specimens from the elderly patient. *Lab Med.* 1997;28:518-522
10) Brigden ML, *et al*. Prothrombin time determination: the lack of need for a discard tube and 24-hour stability. *Am J Clin Pathol.* 1997;108:422-426
11) Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens;* 7th ed. CLSI standard GP41-ED7. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.
12) Larsson BA, *et al*. Venipuncture is more effective and less painful than heel lancing for blood tests in neonates. *Pediatrics.* 1998;101:882-886
13) Berns SD, Matchett JL. Effect of phlebotomy technique on serum bicarbonate values. *Acad Emerg Med.* 1998;5(1):40-44
14) Adcock DM, *et al*. Minimum specimen volume requirements for routine coagulation testing. Dependence on citrate concentration. *Am J Clin Pathol.* 1998;109:595-599
15) Reneke J, *et al*. Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/l (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757
16) Phelan S. Phlebotomy: review guide. Chicago, IL: ASCP Press, 1998
17) Dale JC. Preanalytic variables in laboratory testing. *Lab Med.* 1998;29:540-545
18) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
19) Pruett S. Needle-stick safety for phlebotomists. *Lab Med.* 1998;29:754-760
20) Dale JC, Hamrick HJ. Neonatal bilirubin testing practices. Reports from 312 laboratories enrolled in the College of American Pathologists Excel proficiency testing program. *Arch Pathol Lab Med.* 2000;124:1425-1428
21) Burns ER, Yoshikawa N. Hemolysis in serum samples drawn by emergency department personnel versus laboratory phlebotomists. *Lab Med.* 2002;33:378-380

*****REVISED** 08/17/2016***

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. The patient's identity should be verified by asking the patient to identify him- or herself, when it is practical to do so. 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.*

Evidence of Compliance:

✓ Written collection procedure, including criteria for patient identification

REFERENCES
1) Garza D, Becan-McBride K. Phlebotomy handbook, 2nd ed. Norwalk, CT: Appleton & Lange, 1989
2) Renner SW, *et al*. Wristband identification error reporting in 712 hospitals. A College of American Pathologists' Q-Probes study of quality issues in transfusion practice. *Arch Pathol Lab Med.* 1993;117:573-577

3) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy. 12th edition. Northfield, IL: College of American Pathologists, 2007
4) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207
5) Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens;* 7th ed. CLSI standard GP41-ED7. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.
6) Howanitz PJ, *et al*. Continuous wristband monitoring over 2 years decreases identification errors. A College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2002;126:809-815
7) Clinical and Laboratory Standards Institute (CLSI). Accuracy in Patient and Sample Identification; Approved Guideline. CLSI document GP33-A (ISBN 1-56238-721-9). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010.
8) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1283(a)(2)]

***REVISED** 08/17/2016*

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 in laboratory policy.

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 (e.g. hospital room number) is not an acceptable identifier. Identifiers may be in a machine readable format, such as a barcode.

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. The laboratory should 1) Provide a list of acceptable identifiers to all specimen collectors; 2) Communicate with specimen collectors regarding the importance of this requirement; and 3) Have a procedure for 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:

- ✓ Written policy with criteria for acceptable labeling of primary specimen containers **AND**
- ✓ Specimen collection procedures with defined labeling specifications **OR**
- ✓ Records of audits for compliance with specimen labeling policies and procedures

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.* CLSI document AUTO12-A (ISBN 1-56238-748-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2011.
2) So You're Going to Collect a Blood Specimen. An Introduction to Phlebotomy, 12th edition. Northfield, IL: College of American Pathologists, 2007
3) Clinical and Laboratory Standards Institute. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard. 2nd ed.* CLSI document AUTO02-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2006.
4) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(a)]

GEN.40492 Specimen Label Correction — Phase II

The laboratory has 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 (e.g. 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 (e.g. 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 maintained. 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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1283(a)(3)]

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:

- ✓ Written procedure defining labeling requirements of specimens for pretransfusion testing **AND**
- ✓ Written procedure defining system identifying the individual collecting pretransfusion testing specimens

REFERENCES

1) Wenz B, *et al.* Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16
2) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med*. 1997;28:203-207
3) Sandler SG, Langeberg A, Carty K, Dohnalek LJ. Bar codes and radio-frequency technologies can increase safety and efficiency of blood transfusions. *LabMedicine* 2006;37:436-439
4) Sandler SG, Langeberg A, DeBandi L, Gibble J, Wilson C, Feldman CL. Radio-frequency identification technology can standardize and document blood collections and transfusions. *Transfusion* 2007;47:763-70

*****NEW** 08/21/2017***

GEN.40495 Relationship and Forensic Identity Testing Specimen Collection — Phase II

Specimens collected for relationship and forensic identity testing are collected and processed meeting the following criteria:

1. **Collections are performed by an unbiased, third party individual with no interest in the outcome of the case.**
2. **Collection materials are not in the possession of the tested parties at any time prior to, during, or following the collection procedure.**

3. **The specimens and accompanying documents are shipped to the testing laboratory directly by the collector.**

Evidence of Compliance:

✓ Policies and procedures for specimen collection

REFERENCES
1) Standards for Relationship Testing Laboratories. 12th ed. American Association of Blood Banks. Bethesda, MD; 2016.

***REVISED** 08/21/2017*

GEN.40497 Relationship and Forensic Identity Testing Specimen Collection Data Phase II

For relationship and/or forensic identity testing, the following data are obtained during specimen collection for each person to be tested:

1. **Printed name of person being tested**
2. **Alleged relationship, if applicable**
3. **Date of birth**
4. **Race/ethnic background with the exception of a child being tested**
5. **Place and date of specimen collection**
6. **Printed name, signature, and contact information of person(s) collecting and/or witnessing (if different) the specimen collection**
7. **Photograph or legible photocopy of a picture identification card for each individual tested (government issued ID or other photograph suitable for positive identification**
8. **History of transfusion in the preceding three months or any history of allogeneic hematopoietic progenitor cell transplantation**
9. **Synopsis of case history/investigation, sample source, if applicable for forensic purposes**
10. **Record of informed consent from the individual being tested or individual with legal authority**

NOTE: If the laboratory uses prepackaged kits for specimen collection, any additional instructions that accompany the kit must be followed.

Evidence of Compliance:

✓ Policies and procedures for specimen collection **AND**

✓ Records of specimen collection for relationship and forensic identity testing

REFERENCES
1) Standards for Relationship Testing Laboratories. 12th ed. American Association of Blood Banks. Bethesda, MD; 2016.

***REVISED** 08/21/2017*

GEN.40498 Relationship and Forensic Identity Testing Specimen Labeling Phase II

For relationship and forensic identity testing, information about each individual and the accuracy of the specimen label are verified by that individual or the legal guardian. The affixed label on each specimen contains the following:

1. **At least two unique identifiers, such that each specimen can be unmistakably identified from other specimens in the same case.**
2. **Date of specimen collection**
3. **Initials or signature of the collector verifying the specimen integrity**

Evidence of Compliance:

✓ Records of information and label verification by patient or legal guardian

REFERENCES
1) Standards for Relationship Testing Laboratories. 12th ed. American Association of Blood Banks. Bethesda, MD; 2016.

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. Proper collection techniques are essential.

Evidence of Compliance:

- ✓ Written procedure defining methods for providing feedback to specimen collectors **AND**
- ✓ 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:

- ✓ Written instructions to phlebotomists **AND**
- ✓ Training records

CHAIN-OF-CUSTODY SPECIMEN COLLECTION AND HANDLING

This section applies to laboratories using a chain-of-custody process for collection and/or processing of patient specimens intended for laboratory testing, including laboratories that refer testing to other laboratories or perform the testing on-site. If a chain-of-custody process is not used, this section is not applicable.

Collection and testing performed for medical diagnosis and treatment does not require the use of a chain-of-custody process. The need for a chain-of-custody process is determined by each laboratory based on its setting and services offered. If testing is to be performed following a chain-of-custody process, specimens must follow the chain-of-custody process for the entire process from beginning to the end.

NOTE: This section does not apply to laboratories participating in the Reproductive Laboratory Accreditation Program or the Forensic Drug Testing Accreditation Program.

Inspector Instructions:

	• Sampling of chain-of-custody policies, procedures, and forms (including collection, receiving, accessioning, specimen retention, storage, and record retention) • Sampling of chain-of-custody records
	• Locked limited-access secured area for original specimens/containers, aliquots, and records
	• Who has access to the secure area where original specimens are stored? • What is your course of action when unacceptable specimens are received?

*****NEW** 08/21/2017***

GEN.40502 Chain-of-Custody Procedures **Phase II**

There are written procedures for chain-of-custody specimen collection, accessioning, and handling.

NOTE: If specimens are referred to another laboratory, the collection site must follow chain-of-custody instructions provided by the referral laboratory.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline.* 3rd ed. CLSI Document C52-ED3. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.
2) Wu A et al. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines; Recommendations for the Use of Laboratory Tests to Support Poisoned Patients Who Present to the Emergency Department. *Clinical Chemistry*. 2003;49:(3)357-379.

*****NEW** 08/21/2017***

GEN.40503 Chain-of-Custody Records **Phase II**

The external and internal chain-of-custody records (as applicable) for specimen collection, receiving, accessioning, and handling are complete and include the following:

- **Type of specimen collected**
- **Verification of patient and/or specimen identity**
- **Identification of laboratory-generated aliquots**
- **Verification of the integrity (tamper-evident) of the specimen container**
- **Identity of individuals handling the specimens**
- **Storage location when not in the possession of an authorized individual, including aliquots**
- **Reason for the transfer of custody and date of transfer**

NOTE: If specimens are referred to another laboratory, the collection site must follow chain-of-custody instructions provided by the referral laboratory.

Evidence of Compliance:

✓ Written chain-of-custody procedure **AND**
✓ Completed chain-of-custody records following written procedure

***NEW** 08/21/2017*

GEN.40504 Chain-of-Custody Acceptability Criteria **Phase II**

The chain-of-custody procedure defines criteria for determining the acceptability of specimens and the process followed when unacceptable specimens are identified (i.e. reporting problems to the client).

NOTE: Clients and laboratories may have different rules for evaluating a specimen for its acceptability for analysis (chain-of-custody failures, missing information, specimen leakage, inadequate volume, wrong type of specimen submitted, etc.).

Unacceptable specimens must be monitored by the laboratory as part of its quality management program.

Evidence of Compliance:

- ✓ Specimen rejection records

***NEW** 08/21/2017*

GEN.40506 Secured Specimen Storage **Phase II**

The original specimens (in the original container) and appropriately labeled aliquots are maintained in an appropriate manner when not in the possession of an authorized individual.

NOTE: The original specimens must always be maintained either in the direct custody of an authorized individual or be in a locked secured area accessible only to authorized individuals. This locked and limited-access area may be a refrigerator, freezer, or storage room within the laboratory.

Aliquots or extracts in the laboratory for testing must be in the possession of an authorized individual or be maintained with "line of sight" custody. If the laboratory is a secure, limited access facility, custody of the aliquot may be assigned to an instrument or temporary storage area, as long as records of individual access and egress from the area are recorded.

An authorized individual is considered a person with specific training and work responsibilities for chain-of-custody specimens. General personnel, such as custodians, or technologists not assigned to the chain-of-custody work, must not have unescorted access to secure areas.

Evidence of Compliance:

- ✓ Written policy defining criteria for storage of and access to specimens collected by chain-of-custody procedures **AND**
- ✓ Records for internal chain-of-custody reflecting limited-access storage **OR** record of direct custody of the specimen by an authorized person at all times

***NEW** 08/21/2017*

GEN.40507 Specimen Retention and Storage **Phase II**

Specimen retention and storage conditions are defined for each type of specimen tested by the laboratory using a chain-of-custody procedure.

NOTE: The minimum specimen retention time and storage condition must be defined in laboratory policy and comply with applicable laws and regulations.

***NEW** 08/21/2017*

GEN.40509 Secured Records **Phase II**

The chain-of-custody collection records, security logs, and testing records are retained for an appropriate period of time, no less than two years and following applicable laws

and regulations, in a limited-access, secured (locked) area that is only accessible to authorized laboratory personnel.

NOTE: The laboratory must be able to store these records as long as any legal action is pending and following client/agency requests.

Evidence of Compliance:
- ✓ Written policy addressing restricted access to secured records **AND**
- ✓ Written record retention policy

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.

Inspector Instructions:

	• Sampling of specimen packing and shipping policies and procedures • Sampling of packaging and shipping of infectious materials training records
	• How do you know specimens sent from remote sites are actually received? • What is your course of action when specimens received from remote sites are unacceptable?

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

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

Evidence of Compliance:
- ✓ Written procedure defining criteria for packaging and labeling

REFERENCES
1) World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997
2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication. General. Washington, DC: US Government Printing Office, 1998(Oct 1): [49CFR172]
3) Beckala HR. Regulations for packaging and shipping laboratory specimens. *Lab Med*. 1999;30:663-667
4) Tarapchak P. In 'shipping' shape. *Advance/Lab*. 2000;9(7):48-59

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

The laboratory packages and ships infectious material in accordance with applicable federal, state and local regulations.

Evidence of Compliance:
- ✓ Written procedures for packaging and shipping that comply with regulations

REFERENCES

1) World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997
2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication. General. Washington, DC: US Government Printing Office, 1998(Oct 1): [49CFR172]
3) Clinical and Laboratory Standards Institute. *Quality Control of Microbiological Transport Systems; Approved Standard.* 2nd ed. CLSI Document M40-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

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 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

REFERENCES

1) Title 49, Code of Federal Regulations, Part 172.704 Training Requirements
2) Clinical and Laboratory Standards Institute. *Quality Control of Microbiological Transport Systems; Approved Standard.* 2nd ed. CLSI Document M40-A2. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

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 (e.g. 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

REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/PROCESSING

Inspector Instructions:

	• Sampling of specimen receipt and handling policies and procedures • Sampling of specimen requisitions • Sampling of temperature logs (refrigerator, freezer)
	• How do you know what date/time a specimen is received in your laboratory? How are specimens accessioned once received by the laboratory? • What is your course of action regarding verbal orders? • How do you know your specimen containers do not contribute to analytic interference?
	• If lost specimens are a recurring problem, further evaluate the laboratory's investigation of where/how in the process the specimen was lost and the corrective actions that were implemented

GEN.40700 Requisitions **Phase II**

All specimens are accompanied by an adequate requisition.

NOTE: In computerized settings, there may not be a paper requisition that is physically attached to the specimen container.

REFERENCES
1) Valenstein P, Howanitz PJ. Ordering accuracy: a College of American Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med.* 1995;119:117-122
2) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7162 [42CFR493.1241(a)]

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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7162 [42CFR493.1241(e)]

GEN.40750 Requisition Elements — Phase II

The paper or electronic requisition includes all of the following elements, as applicable.

1. **Adequate patient identification information (*e.g.*, 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 gynecologic specimens)**
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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7162 [42CFR493.1241(c)]
2) Valenstein P, Howanitz PJ. Ordering accuracy: a College of American Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med.* 1995;119:117-122
3) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150

GEN.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.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard. 2nd ed.* CLSI document AUTO02-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2006.

GEN.40900 Specimen Date Received — Phase II

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(b)]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1283(a)(2)]

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).

Evidence of Compliance:

✓ Written policy requiring test orders by authorized persons, if applicable in the jurisdiction in which the laboratory is located

REFERENCES
1) Shulze. Microscope on Washington. Direct-access testing: a state-by-state analysis. *Lab Med.* 1999;30:371-373
2) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150

GEN.40932 Verbal Test Authorization — Phase II

For laboratories subject to US regulations, the laboratory solicits written or electronic authorization for verbal orders within 30 days.

NOTE: The laboratory must retain the written authorization or record of efforts made to obtain a written authorization. In a managed office where the staff assistants are not employees of the physician/clinician, the staff should not sign a test requisition for the physician without some type of provider services agreement. This agreement must specify how the clinician has accepted responsibility for the tests ordered from the off-site laboratory. (This situation is different from the hospital environment, where the physician has personally signed the order sheet.)

Evidence of Compliance:

✓ Records of follow-up to obtain written order

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7162 [42CFR493.1241(a),1241(b)]
2) Shulze. Microscope on Washington. Direct-access testing: a state-by-state analysis. *Lab Med.* 1999;30:371-373
3) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150

GEN.40935 Test Order Read Back — Phase II

The laboratory has a policy that 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 has a policy on confirmation of test orders that may be unclear (*e.g.* orders using non-standard or non-specific terms).

*****REVISED** 08/21/2017***

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 (e.g. 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 (e.g. 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. For specimens collected for alcohol testing, both metabolic consumption of alcohol and production of alcohol by microorganisms must be considered.

Evidence of Compliance:

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

REFERENCES

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13) Yared M, *et al*. Time dependent absorption of drugs by the barrier gel of the Greiner Vacuette blood collection tubes: impact on therapeutic drug monitoring. *Am J Clin Pathol.* 2000;114:302
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18) Hashim IA. Blood samples collected in serum-separator tubes give higher free tri-iodothyronine levels using the Immulite assay. *Clin Chem.* 2001;47(suppl):A14
19) Clinical and Laboratory Standards Institute (CLSI). Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline. CLSI document GP34-A (ISBN 1-56238-739-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2010.

GEN.41017 Centrifuge Operating Speeds — Phase II

The operating speeds of centrifuges are checked at least annually as needed for the intended use, and this is done in a safe manner.

NOTE: For centrifuges with 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

REFERENCES

1) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

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GEN.41042 Refrigerator/Freezer Temperatures — Phase II

Refrigerator/freezer temperatures are checked and recorded daily using a calibrated thermometer.

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 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 (e.g. 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.

A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised. Storage conditions must remain within the specifications of the manufacturer of the reagent or control. Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer. Thermal containers within the freezer may be used.

Patient samples may be stored in frost free freezers only if protected from thawing. The laboratory must maintain records showing that the temperatures stay within the defined range.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(b)(2)]

RESULTS REPORTING AND REFERRAL OF TESTING

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-A2]. 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 (i.e. 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.

Inspector Instructions:

	• Sampling of reporting policies and procedures • Sampling of paper or electronic laboratory reports • Sampling of referral laboratory's patient reports • Patient confidentiality policies and procedures
	• How does the laboratory director ensure that the content of laboratory reports effectively communicates patient test results? • How does the laboratory protect patient information? • What is your course of action if laboratory testing is delayed? How frequently does this occur? • What is your process for selecting referral laboratories? • How does your laboratory determine who is authorized to receive results? • How does your laboratory archive test results for comparison with later results?
	• If instances of delayed test reporting are frequent, further evaluate laboratory director leadership's investigation, corrective actions, and resolution

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 (whether paper or computer screen images) 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 Results **Phase I**

There is a policy for laboratory director input regarding whether outside laboratory results are reported through the primary reporting system (*i.e.* the laboratory information system or the institution's electronic medical record).

NOTE: At times patients may bring test results from outside laboratories to their physicians. Patients' physicians may request, or institutional policy may dictate, that such results (or other test results from outside laboratories) be integrated into the laboratory's primary reporting system (i.e. the LIS or the institution's electronic medical record). The laboratory director should be aware of whether results from outside laboratories are reported through the laboratory information system or the electronic medical record system. It is recognized that the laboratory director may not be in a position to prohibit entry of outside laboratory results into the electronic medical record system.

However, if such results are integrated, the name and address of the outside laboratory must be available in the primary reporting system, and there must be an indication available to the person viewing such results that the results originated from an outside laboratory. Criteria for inclusion of such results might include whether the quality of the outside laboratory has been evaluated by the laboratory director; CLIA licensure or equivalent; whether reference intervals and/or units of measurement differ from in-house tests; whether units of measurement and reference intervals are included; and possession of an official report.

If the laboratory director believes that certain test results should not be integrated into the primary reporting system, one option is to include such results in a section of the electronic medical record other than the laboratory database.

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**
3. **Name of physician of record, or legally authorized person ordering test, as appropriate**
4. **Date of specimen collection, and if appropriate, time of collection**
5. **Date of release of report (if not on the report, this information should be readily accessible)**
6. **Time of release of report, if applicable (if not on the report, this information should be readily accessible)**
7. **Specimen source, when applicable**
8. **Test result(s) and units of measurement, when applicable**
9. **Reference intervals, as applicable**
10. **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.)

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.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.

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.

REFERENCES
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4) Rochman H. Clinical pathology in the elderly. New York: Karger, 1988:207216
5) Tietz NW, ed. Clinical guide to laboratory tests. Philadelphia: WB Saunders, 1990
6) Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory - Approved Guideline- Third Edition - CLSI Document EP28-A3C. (ISBN 1-56238-682-4) Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, PA, 19087-1898, USA, 2010.
7) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(h)(i)(3)] and [42CFR493.1283(a)(1)]

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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(b)]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7163 [42CFR493.1291(j)]

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 (e.g. 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)

REFERENCES
1) Title 45 – Code of Federal Regulations – Parts 160, 162, and 164, Health Insurance Reform: Security Standards; Final Rule, *Federal Register*, Published Feb. 20, 2003.

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

There is a written policy to ensure 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.

Under the HIPAA Privacy Rule, 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 to have 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.

For additional information see Department of Health and Human Services, Medicare and Medicaid Services, "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule." Fed Reg 79:7290 (2014); 45CFR164.502(g); 45CFR164.514.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2014(Feb 6):7289 [42CFR493.1291(l)]

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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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7162 [42CFR493.1283(a)(4)]
2) Clinical and Laboratory Standards Institute. *Autoverification of Clinical Laboratory Test Results; Approved Guideline.* CLSI document AUTO10-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2006.

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.

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2004(Oct 1):1048 [42CFR493.1291(k)]

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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: 1. 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).

2. 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).

3. 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.

4. 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.

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(k)(3)]

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.

GEN.41316 Infectious Disease Reporting — Phase II

There is a policy regarding the timely communication, and documentation thereof, of diagnoses of infectious diseases of particular significance (*e.g.* human immunodeficiency virus and tuberculosis).

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

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.

GEN.41325 Newborn Screening Results — Phase II

There must be a procedure 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.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Newborn Screening Follow-up.* CLSI document NBS02-A2. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA

GEN.41345 Turnaround Time **Phase II**

The laboratory has defined turnaround times (*i.e.* the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and it has a policy for notifying the requester when testing is delayed.

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.

Evidence of Compliance:

✓ Written policy defining test reporting turnaround time and process for communication of delays in turnaround time

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1291(h)]
2) Winkelman JW. How fast is fast enough for clinical laboratory turnaround time? Measurement of the interval between result entry and inquiries for reports. *Am J Clin Pathol.* 1997;108:400-405
3) Manor PG. Turnaround times in the laboratory: a review of the literature. *Clin Lab Sci.* 1999;12(2):85-89
4) Eggert AA, *et al.* Using detailed computer tracking to monitor and improve outpatient phlebotomy service and overall test turn-around time. *Clin Chem.* 2000;46:A71

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

The laboratory has a written procedure 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 not covered by CLIA (e.g. histology), 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 (*e.g.* problem log, review of reports)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1034 [42CFR493.1242(c)]
2) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Qualifying, Selecting and Evaluating a Referral Laboratory Approved Guideline—Second Edition. CLSI document QMS05-A2 (ISBN I-56238-855-X [Print], ISBN I-56238- 856- 8 [Electronic]. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.
3) Caro B. Department dollars. Planning a referral testing service program. *Advance/Lab.* 1999;8(4):22-24
4) Brooks B. Cost considerations of esoteric testing. *Advance/Lab.* 1999:8(6):59-68
5) Carter JE, Bennett B. Laboratory "send out" test review by pathology house staff: cost-cutting strategy. *Am J Clin Pathol.* 1999;112:572
6) Department of Defense instructions 6440.2, Clinical Laboratory Improvement Program, April 20, 1994.

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(h)(i)(2)]

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7163 [42CFR493.1291(h)(i)(1)]

DIRECT-TO-CONSUMER TESTING

NOTE: Direct-to-consumer (DTC) tests are defined as tests that are requested or ordered by the consumer. All applicable requirements in other areas of the checklists apply to direct-to-consumer testing. This checklist section applies only to laboratories subject to US regulations. This checklist section does not apply to health fairs.

Inspector Instructions:

- Direct-to-consumer testing policies and procedures
- Sampling of direct-to-consumer laboratory reports

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GEN.41460 DTC Jurisdiction **Phase II**

The laboratory performs DTC testing and reports results of DTC tests only in jurisdictions where such testing is lawful.

NOTE: No less than every two years, the laboratory must verify which jurisdictions permit DTC testing if it provides direct-to-consumer testing. The scope of testing performed must be limited to those allowed under the applicable law.

Evidence of Compliance:

✓ Record that the laboratory has reviewed applicable laws/regulations

GEN.41475 DTC Report **Phase II**

The test report includes test results, reference intervals, interpretation as applicable, and limitations of the test, as applicable, in language readily understandable by a lay person.

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GEN.41485 DTC Report **Phase II**

The test report includes information that helps the consumer to contact a licensed heath care professional about the clinical significance of the test result.

NOTE: This information may consist of the name, phone number, and email address of a health care professional. Alternatively, it may be the phone number of an office at the laboratory or medical center or website that can provide contact information to the consumer.

GEN.41497 DTC Result Retention **Phase II**

The laboratory retains the results of DTC tests and reference intervals for at least 10 years after testing.

NOTE: This requirement applies only to DTC tests performed after June 15, 2009.

QUALITY OF WATER AND GLASSWARE WASHING

Inspector Instructions:

	• Water quality policies and procedures • Water quality test records
	• How does your laboratory clean glassware?

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 should 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:

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.

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

Evidence of Compliance:

- ✓ Procedures for water quality testing **AND**
- ✓ Records of water quality testing **AND**
- ✓ Record of corrective action when water quality does not meet specifications

REFERENCES

1) Gabler R, *et al*. Degradation of high-purity water on storage. *J Liquid Chromatogr.* 1983;6:2565-2570
2) Mather J, *et al*. The effects of water purity and addition of common water contaminants on the growth of cells in serum-free media. *BioTechniques.* 1986;4:56-63
3) Gould MJ. Evaluation of microbial/endotoxin contamination using the LAI test. *Ultrapure Water.* 1993;10:43-47
4) Huang YH, *et al.* Comparison of Milli-Q PF Plus water to DEPC-treated water in the preparation and analysis of RNA. *BioTechniques.* 1995;19:656-661
5) Paul DH. Ion exchange primer. *Ultrapure Water.* 1997;14:63-66
6) Clinical and Laboratory Standards Institute. *Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline*. 4th ed. CLSI document GP40-A4-AMD. Clinical and Laboratory Standards Institute, Wayne, PA, 2012.
7) Srikanth B. Ultraviolet light: recent advancements in UV technology yield enhanced TOC reduction performance. *Ultrapure Water.* 1998;15:40-46
8) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med.* 2000;31:605-611

GEN.41770 Glassware Cleaning — Phase II

There are written procedures for handling and cleaning glassware, including methods for testing for detergent removal.

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

A simple procedure to check for detergent residue uses bromcresol purple (0.1 g bromcresol purple in 50 mL ethyl alcohol). Pipette approximately 5 cm (2 inches) distilled water into a representative, washed, glassware item. Add two to three drops bromcresol solution. A purple color reveals residual detergent. A yellow color indicates satisfactory rinsing.

Evidence of Compliance:

- ✓ Records of detergent residue testing

REFERENCES

1) Clinical and Laboratory Standards Institute. *Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline.* CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

LABORATORY COMPUTER SERVICES

Multiple solutions for laboratory information systems (LIS) exist. Traditional systems have a local "host" database (i.e. 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*

Inspector Instructions:

- CAP accreditation certificate of remote site or records that the host site is in compliance with this section of the checklist

GEN.42195 Remote LIS **Phase II**

If components of the LIS are located at a facility other than the one under this CAP accreditation number, there is evidence that the remote facility complies with CAP requirements for host LIS functions.

NOTE: This requirement does not apply if all components of the LIS are under the laboratory's CAP number. This requirement may be addressed by a copy of the CAP accreditation certificate from other sites, or evidence that the computer facility has been provided a copy of this Checklist, and has satisfactorily addressed the contents of the Computer Facility section, and all other pertinent requirements, with records provided to the laboratory director and the CAP inspector.

COMPUTER FACILITY

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

Inspector Instructions:

- Computer facility equipment and location (clean, ventilated, protected against power surges)
- Fire extinguishers/equipment

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 (extinguishers) is appropriate for electrical components available.

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, e.g. 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.

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) National Fire Protection Association Standard 75: Protection of Information Technology Equipment, 2013 edition. Chapter 8.
3) Occupational Safety and Health Administration. Portable fire extinguishers. Hydrostatic testing. Washington, DC: US Government Printing Office, 2002(Jul 1): [29CFR1910.157(f)]

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 (e.g. 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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(b)(4)]

HARDWARE AND SOFTWARE

Inspector Instructions:

- Sampling of computer training records

- How does your laboratory verify the LIS following a hardware or software failure?
- Who do you notify when there is a computer malfunction?

***REVISED** 08/21/2017*

GEN.43022 LIS Testing **Phase II**

There are records that programs are adequately tested for proper functioning when first installed and after any modifications, and that 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. 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. Records must be retained for at least two years beyond the service life of the system.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Managing and Validating Laboratory Information System: Approved Guideline*. CLSI document AUTO08-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2006

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.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Managing and Validating Laboratory Information System: Approved Guideline*. CLSI document AUTO08-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2006

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**

There is a written procedure with instructions for contacting a responsible person (*e.g.* Computer System Manager) in case of computer malfunction.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1251(b)(14)]

SYSTEM SECURITY

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

Inspector Instructions:

- Sampling of computer security policies and procedures

***REVISED** 08/21/2017*
GEN.43150 User Authentication **Phase II**

There are explicit written policies that specify who may access the computer system, how the access is obtained, and how the security of access is maintained (e.g. inactivated when personnel leave, not posted on terminals).

NOTE: The laboratory should establish security (user) codes to permit only specifically authorized individuals to access patient data or alter programs. Examples of best practices include: periodic alteration of passwords by users; minimum character length for passwords; password complexity requirements (e.g. 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 should 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.

REFERENCES
1) Datta S. Bettinger K, Snyder M. Secure cloud computing for genomic data. Nat Biotechnol. 2016;34(6):599-91. doi:10.1038/nbt.3496.
2) Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq.
3) Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), codified at 42 U.S.C. § 300gg and 29 U.S.C. § 1181 et seq. and 42 USC 1320d et seq. Health Insurance. Accessed February 3, 2017.
4) Modification to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule (HIPAA Omnibus Rule) (2013), 45 CFR § 160, 164. HIPAA Privacy. Accessed February 3, 2017.
5) Health Insurance Reform: Security Standards (Final Security Rule) (2003), 45 CFR §§ 160, 162. 2003. Insurance Reform. Accessed February 3, 2017.

***REVISED** 08/21/2017*
GEN.43200 User Authorization Privileges **Phase II**

There are written procedures and access privileges in place to confine the level of access of authenticated users to those functions they are authorized to use to fulfill their job responsibilities.

NOTE: The laboratory should establish user roles and/or policies that define those who may only access patient data and users who are authorized to enter patient results, change results, or alter computer tables or programs. Personnel user rights should 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 (e.g. pharmacy or medical records), policies must prevent unauthorized access to the data through the LIS to permit only specifically authorized individuals to access patient data or alter programs.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Managing and Validating Laboratory Information System: Approved Guideline*. CLSI document AUTO08-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2006
2) Clinical and Laboratory Standards Institute. *Information Technology Security of* in vitro *Diagnostic Instruments and Software Systems; Approved Standard. 2nd ed.* CLSI document AUTO11-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2014.

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

There are written policies and procedures that govern installation of software on any computer used by the laboratory.

NOTE: Laboratory computers often serve multiple functions. Many of these computers are connected in a network. The security of the system should 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.

***REVISED** 08/21/2017*
GEN.43325 Public Network Security **Phase II**

If the facility uses a public network, such as the Internet as a data exchange medium, there are network security measures in place to ensure confidentiality of patient data.

NOTE: Patient information sent over a public domain such as the Internet or stored in "the cloud," is considered "potentially public." Thus it may be accessible to some 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 information, encryption at rest and encryption in transit should be implemented to ensure network and data security.

Evidence of Compliance:
✓ Written policy defining mechanism for data protection

REFERENCES
1) Clinical and Laboratory Standards Institute. *Managing and Validating Laboratory Information System: Approved Guideline*. CLSI document AUTO08-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2006

PATIENT DATA

Inspector Instructions:

READ	• Records of the review of patient results containing calculated data
ASK	• How are absurd values detected? • How does the technologist electronically enter comments regarding specimen quality? • How does your laboratory verify manual and automated result entry?

GEN.43450 Calculated Patient Data Verification **Phase II**

Calculated values reported with patient results are reviewed every two years or when a system change is made that may affect the calculations.

NOTE: This checklist requirement applies only to calculations based on formulas modifiable by the user.

Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked to ensure accuracy and records retained. This requirement applies to laboratory information systems, middleware, and analyzers. More frequent checks may be required for certain specific calculations, as delineated elsewhere in the checklists (e.g. 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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(a)]

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

The system provides for comments on specimen quality that might compromise the accuracy of analytic results (*e.g.* 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 data or control files.

NOTE: When individual tests from a single test order (e.g. 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.

REFERENCES

1) Jones JB. The importance of integrating POCT data into an organized database. *Advance/Laboratory*. 1999;8(9):8-10
2) Halpern NA, Brentjens T. Point of care testing informatics. The critical care-hospital interface. *Crit Care Med.* 1999;15:577-591

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).

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(a)]

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

There are written procedures to ensure reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system.

REFERENCES
1) Valenstein P, *et al.* Laboratory computer availability. A College of American Pathologists Q-Probes study of computer downtime in 422 institutions. *Arch Pathol Lab Med.* 1996;120:626-632

AUTOVERIFICATION

Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, where they are compared against laboratory-defined acceptance parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats without any additional laboratory staff intervention. Any data that fall outside the defined parameters are reviewed by laboratory staff prior to reporting.

Inspector Instructions:

- Autoverification policies and procedures
- Autoverification validation records

GEN.43875 Autoverification Validation **Phase II**

There is documentation that the autoverification process was validated initially, and is tested at least annually and whenever there is a change to the system that could affect the autoverification logic.

NOTE: The range of results for which autoverification is acceptable must be defined for all patient tests subject to autoverification.

Validation of autoverification must include a process to confirm that the autoverification algorithm decision rules are functioning properly, including the use of previously assayed specimens with results that challenge the algorithm. Examples of specimens that may be needed to validate the autoverification algorithm decision rules may include specimens with analyte concentrations within the normal reference limit, above or below the reference limits, above or below the analytic measurement range, and in the critical range. Specimens with known interferences and specimens that require calculations should also be used, when applicable.

When changes are made that might affect the autoverification decision algorithm, validation appropriate to the scope and nature of the change must be performed.

Evidence of Compliance:

- ✓ Records of autoverification validation studies approval **AND**
- ✓ Records of ongoing retesting of the autoverification process at least annually and at changes to the system

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Autoverification of Clinical Laboratory Test Results: Approved Guideline*. CLSI document AUTO10-A (ISBN 1-56238-620-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

GEN.43878 Autoverification QC Samples — Phase II

For all test results subject to autoverification, the laboratory ensures that applicable quality control samples have been run within an appropriate time period, with acceptable results.

NOTE: This requirement may be met by, 1) the computer system automatically checking quality control status prior to autoverification, or, 2) manually disabling autoverification after any unacceptable QC result, or when QC has not been run within the required time interval.

Evidence of Compliance:

- ✓ Procedure defining the QC process **AND**
- ✓ QC data to show that QC was performed at defined intervals

GEN.43881 Autoverification Results — Phase II

Results are compared with an appropriate range of acceptable values and flags or warnings reviewed prior to autoverification.

NOTE: Appropriate comparisons include checking patient results against absurd and critical results requiring manual intervention (repeat testing, dilution, telephone notification of results, etc.)

The mere presence of a flag may not disqualify a result from autoverification, but any flag that is not specifically recognized by the autoverification program must cause the flagged result to be held for manual review.

Evidence of Compliance:

- ✓ Records of system rules including comparison of patient results against absurd and critical values

GEN.43887 Autoverification Audit Trail — Phase I

The audit trail in the computer system identifies all test results that were autoverified, and the date/time of autoverification.

GEN.43890 Autoverification Delta Checks — Phase I

The autoverification process includes all delta checks that the laboratory performs prior to manual release of test results.

NOTE: This requirement does not require delta-checking for all autoverified results, but the laboratory's delta-checking procedures should be the same for manually released and autoverified test results.

Evidence of Compliance:

- ✓ Records of system rules including the use of delta checks when appropriate

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Fed Register.* 2003(Jan 24): [42CFR493.1281(b)(1-5)]

GEN.43893 Autoverification Suspension **Phase II**

The laboratory has a procedure for rapid suspension of autoverification.

NOTE: Laboratory personnel should be able to suspend autoverification in the event of a problem with a test method, analytic instrument or the autoverification program.

DATA RETRIEVAL AND PRESERVATION

Inspector Instructions:

READ	• Data preservation policies and procedures
DISCOVER	• If there are indications that the computer system is inadequate to meet the patient needs of the organization, further evaluate laboratory/LIS leadership's responses, corrective actions, and resolutions

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.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(b)]
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24):7163 [42CFR493.1291(j)]

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**

There are written procedures for the preservation of data and equipment in case of an unexpected destructive event (*e.g.* fire, flood), 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 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.

REFERENCES
1) Valenstein P, *et al*. Laboratory computer availability. A College of American Pathologists Q-Probes study of computer downtime in 422 institutions. *Arch Pathol Lab Med.* 1996;120:626-632
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(b)(4)]
3) Clinical and Laboratory Standards Institute. *Planning for Laboratory Operations During a Disaster; Approved Guideline.* CLSI document GP36-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

INTERFACES

Inspector Instructions:

	• Interface systems policies and procedures • Sampling of reports transmitted to each interfaced system (laboratory data entry of results match patient reports, including reference intervals and comments)
	• How does your laboratory verify the accuracy of data transmission from the LIS to interfaced systems?

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.

*****REVISED** 08/21/2017***
GEN.48500 Interface Result Integrity **Phase II**

There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).

NOTE: Verification must be performed prior to implementation of an interface (i.e. pre go-live) and whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results. In addition, it must be reverified at least every two years. This includes evaluation of data transmitted from the LIS to other computer systems and their output devices.

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 (e.g. 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 (e.g. the same installed instance of an electronic medical record system), validation need only occur for the interface (i.e. at one of the sites) and not for each individual site that is served by that single installed system.

Interface validation should include examples of individual results, test packages or batteries, abnormal flags, and results with reference intervals and comments/footnotes. Initial interface validation should 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

REFERENCES

1) Cowan DF, *et al*. Validation of the laboratory information system. *Arch Pathol Lab Med.* 1998;122:239-244
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(a)]
3) Clinical and Laboratory Standards Institute. *Managing and Validating Laboratory Information System: Approved Guideline*. CLSI document AUTO08-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2006

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

There are 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.

REFERENCES

1) Valenstein P, *et al.* Laboratory computer availability. A College of American Pathologists Q-Probes study of computer downtime in 422 institutions. *Arch Pathol Lab Med.* 1996;120:626-632
2) Clinical and Laboratory Standards Institute. *Information Technology Security of* in vitro *Diagnostic Instruments and Software Systems; Approved Standard. 2nd ed.* CLSI document AUTO11-A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2014.

TELEPATHOLOGY AND REMOTE DATA ASSESSMENT

This section applies to telepathology, in which a digitized or analog video, still image(s), or other data files (e.g. flow cytometry files, Sanger sequencing data) are examined and an interpretation is rendered at an off-site or remote location and that interpretation is included in a formal diagnostic report or 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. This section may be applied to, but is not limited to the disciplines of anatomic pathology, cytopathology, hematopathology, cytogenetics, flow cytometry, histocompatibility, and molecular pathology.

Requirements for remote data assessment do not apply to testing performed within the laboratory using the laboratory's validated software (e.g. pathologist office using a network or virtual private network (VPN) connection).

Telepathology modes include:

- *Static telepathology – interpretation based on pre-selected still image(s)*
- *Dynamic telepathology - viewing real-time images (includes robotic microscopy, video streaming, and desktop sharing)*
- *Virtual slides/whole slide imaging*

This checklist section applies to:

- *Primary diagnoses made by telepathology*
- *Frozen section diagnoses*
- *Formal second-opinion consultations*

- *Ancillary techniques in which the pathologist participates in interpretation of images*
- *Real-time evaluation of FNA specimens for triaging and preliminary diagnosis*

This checklist section is NOT applicable to:
- *Informal reviews without formal reporting*
- *Educational or research use of these systems*

References:
Pantanowitz L, Dickinson K, Evans AJ, Hassell LA, Henricks WH, Lennerz JK, et al. American Telemedicine Association clinical guideline for telepathology. J Pathol Inform. 2014;5:39.

Inspector Instructions:

- Sampling of telepathology policies and procedures
- Sampling of reports generated from reviews of images/slides and data files performed by telepathology

***REVISED** 08/17/2016*
GEN.50057 Slide/Images/Data File Patient Identification **Phase II**

There is a method for the individual reviewing cases to ensure correct patient identification for slides/images and data files submitted for review.

NOTE: There are multiple ways to accomplish positive patient identification, including verbal communications, images of slide identifier, etc.

Evidence of Compliance:
✓ Written procedure defining mechanism to positively identify slides/images and data files

***REVISED** 08/17/2016*
GEN.50614 Clinical Information Access **Phase I**

The individual reviewing cases has access to pertinent clinical information at the time of slide/image(s) or remote data file review.

NOTE: Typically this information includes at least the information on the requisition form.

***NEW** 08/17/2016*
GEN.50630 Telepathology System Validation **Phase I**

The laboratory validates telepathology systems used for clinical diagnostic purposes by performing its own validation studies, including approval for use by the laboratory director (or designee who meets CAP director qualifications) before the technology is used for the intended diagnostic purpose(s).

NOTE: The specific components of the validation study are left to the discretion of the laboratory. As general guiding principles, the validation process should:
- *Closely emulate the real-world clinical environment and involve specimen preparation types and clinical settings relevant to the intended use(s).*
- *Be carried out by a pathologist(s) adequately trained to use the system.*

Refer to GEN.52920 for requirements on validation of whole slide imaging.

Evidence of Compliance:
✓ Records of completed validation study with review and approval

***REVISED** 08/17/2016*

GEN.51728 Telepathology Training **Phase I**

The lab has a procedure addressing training requirements for all users of the telepathology system.

NOTE: The training procedure should be role-specific, as defined in the approved laboratory procedures. Retraining may be required when significant system changes are made.

Evidence of Compliance:

✓ Records for telepathology training in personnel files

***REVISED** 08/21/2017*

GEN.52842 Patient Confidentiality - Telepathology and Remote Data Assessment **Phase II**

There are procedures in place to ensure that sites engaging in telepathology and remote data assessment provide reasonable confidentiality and security.

NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions. These security considerations must be particularly adhered to when using mobile devices in public places.

For laboratories subject to US regulations, the procedures must be in conformance with HIPAA requirements.

GEN.52850 Telepathology Result Records **Phase I**

The telepathology records include diagnoses made and statements of adequacy assessment, preliminary diagnosis, or recommendations for additional studies provided at the time of evaluation.

NOTE: Such records are not required to be included on the patient report.

Evidence of Compliance:

✓ Reports generated from reviews of images/slides and data files performed by telepathology

GEN.52860 Quality Management Program **Phase I**

Telepathology services are included in the laboratory's quality management program.

NOTE: For example, the laboratory might monitor the frequency of deferral cases, comparison to on-site evaluation, or consultation using traditional glass slide microscopy.

WHOLE SLIDE IMAGING

This section applies to laboratories using whole slide imaging systems for diagnostic purposes (primary and/or consultation).

Inspector Instructions:

- Sampling of training records
- System validation records

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GEN.52900 Whole Slide Imaging User Training **Phase I**

There are records showing that all users of the whole slide imaging system have been trained.

NOTE: Users of the whole slide imaging system include individuals responsible for slide scanning and digital slide quality assessment, as well as pathologists. The training procedure should include role-specific training, as defined in the approved laboratory procedures. Retraining may be required when significant system changes are made.

Evidence of Compliance:

✓ Records for whole slide image training in personnel files

GEN.52920 Whole Slide Imaging System Validation **Phase I**

The laboratory validates whole slide imaging systems used for clinical diagnostic purposes by performing its own validation studies, including approval for use by the laboratory director (or designee who meets CAP director qualifications) before the technology is used for the intended diagnostic purpose(s).

NOTE: The specific components of the validation study are left to the discretion of the laboratory.

As general guiding principles, the validation process should:

- *Closely emulate the real-world clinical environment and involve specimen preparation types and clinical settings relevant to the intended use(s);*
- *Be carried out by a pathologist(s) adequately trained to use the system;*
- *Assess intraobserver concordance between digital and glass slides;*
- *Encompass the entire whole slide imaging system, with reevaluation if a significant change is made to a previously validated system.*

Evidence of Compliance:

✓ Records of completed validation study with review and approval

REFERENCES

1) Pantanowitz *et al*, Validating whole slide imaging for diagnostic purposes in pathology: Guideline from the College of American Pathologists Pathology and Laboratory Quality Center. *ARPA*, 2013
http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2013-0093-CP
http://www.cap.org/apps/docs/membership/wsi_faqs.pdf
2) Validation of Digital Pathology in Healthcare Environment: A Whitepaper from the Digital Pathology Association, 2011
http://digitalpathologyassociation.org/_data/files/DPA-Healthcare-White-Paper--FINAL_v1.0.pdf

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 (e.g. 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.

Inspector Instructions:

- Sampling of personnel policies and procedures
- Organizational chart or narrative description
- Sampling of competency assessments for assessment of all six elements of competency for each nonwaived test system, six month competency for new

employees, and assessments done by qualified individuals based on complexity of testing performed
- Sampling of technical personnel files for educational qualifications, (e.g. diplomas, transcripts, primary source verification reports), laboratory personnel licenses (where required), training, and continuing education records for testing personnel, section directors/technical supervisors, supervisors/general supervisors, and consultants using the table below
- Records of diploma/transcript equivalency evaluation for non-US trained personnel by a foreign credentialing agency (for laboratories subject to US regulations)

Sampling to include a mix of the following: 1) laboratory personnel (including MD, DO, PhD, technicians and technologists) and non-laboratory personnel (e.g. POC, PPT, Radiology, Respiratory); 2) full and part-time employees on all shifts and throughout all departments; 3) supervisory staff and testing personnel.

All newly hired personnel for the last two years must be reviewed (if applicable), both laboratory and non-laboratory.

If any documents are missing from the personnel files, record the appropriate deficiency on the Inspector's Summation Report, noting the specific instances of non-compliance.

DO NOT allow laboratory staff to select which personnel records to review. Randomly select specific individuals from the Laboratory Personnel Evaluation Roster following sampling instructions described above. Use the following criteria to determine the number of personnel records to be reviewed:

Total Number of Personnel (both laboratory and non-laboratory)	**Number of Personnel Records to Sample** ****Records of all technical personnel hired within the last two years must be reviewed**
Up to 10	Review all personnel
11 - 100	8 -10
101 - 250	10 -12
251 - 400	13 - 15
401 - 500	16 - 18
More than 500	18 - 20

- Do you have a specific example of an employee who demonstrated unacceptable competency assessments? What were the corrective actions?
- What continuing education classes are available to employees?
- If primary source verification reports are used, what is your process to ensure that the reports contain the required elements?
- How are records of educational qualifications (e.g. diploma or transcript) maintained for point of care and other testing personnel performing nonwaived testing outside of the main laboratory?

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 form.

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** 08/17/2016*

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

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

The technical supervisor must meet the following requirements:

1. *MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with certification in anatomic pathology or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications equivalent to those required for certification.*
   - *If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology or possess equivalent qualifications*
   - *If responsible for clinical pathology must be board certified in clinical pathology or possess equivalent qualifications*
   - *If responsible for anatomic pathology and/or cytopathology, and clinical pathology, must be board certified in both anatomic and clinical pathology or possess equivalent qualifications **OR***
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, physical, biological or clinical laboratory science from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*; or*
   - *Master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or*
   - *Bachelor's degree in a chemical, physical, or biological 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.*

For laboratories subject to US regulations, alternate qualifications for the following specialty areas can be found in Fed Register. 1992 (Feb 28): 7177-7180 [42CFR493.1449]: bacteriology, mycobacteriology, mycology, parasitology, virology, cytology, ophthalmic pathology, dermatopathology, oral pathology, and radiobioassay.

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

For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization.

The 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 results are not reported until corrective actions are taken and test systems are functioning properly*
- *Identification of training needs*

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

Evidence of Compliance:

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7180 [42CFR493.1451]

*****REVISED** 08/21/2017***

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 form.

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

1. *Bachelor's degree in a chemical, physical, biological or clinical 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 with at least two years of training and/or experience in high complexity testing*; or*
3. *Have previously qualified or could have qualified as a general supervisor prior to 2/28/1992*

**The general supervisor's training and experience must be in the designated discipline or area of service for which the individual is responsible.*

Requirements for the supervisors/general supervisors of cytopathology and histocompatibility are more stringent and are found in the Cytopathology and Histocompatibility Checklists.

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

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

Evidence of Compliance:

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7182 [42CFR493.1463]

TECHNICAL AND CLINICAL CONSULTANT

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

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.

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GEN.53625 Technical Consultant Qualifications/Responsibilities Phase II

Technical consultants meet defined qualifications and fulfill expected responsibilities.

NOTE: This requirement applies to all laboratories that are performing any moderate complexity testing. It is not applicable if the laboratory only performs high complexity testing. For moderate complexity testing, one or more individuals qualified as a technical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster form.

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

- *MD or DO, licensed to practice medicine in the jurisdiction where the laboratory is located (if required), with certification in anatomic and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification; or*
- *MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), with at least one year of training and/or experience in nonwaived testing*; or*
- *Doctoral or master's degree in a chemical, physical, biological or clinical laboratory science from an accredited institution with at least one year of training and/or experience in nonwaived testing*; or*
- *Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution with at least two years of training and/or experience in nonwaived testing*.*

**The technical consultant's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible.*

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

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 competency of personnel performing moderate complexity testing, if this duty is delegated, in writing, by the laboratory director. Other responsibilities of the technical consultant include:

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

Evidence of Compliance:

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):101053 [42CFR493.1411] and 2003(Oct 1) 1053-54 [42CFR493.1413]

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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 form.

Clinical consultants must be an MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required) or doctoral scientist certified by an HHS-approved board.

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

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 reports include pertinent information required for interpretation. See TLC.10440, TLC.10500, and TLC.10700.

Evidence of Compliance:

- ✓ Records of clinical consultant qualifications (i.e. 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 (e.g. meeting minutes, activity logs, signed summaries or data with evidence of review)

REFERENCES

1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1415], [42CFR493.1417], [42CFR493.1419]

ALL PERSONNEL

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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.

***NEW** 08/17/2016*

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 (e.g. 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.

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.

Evidence of Compliance:

- ✓ Written policy for continuing laboratory education

REFERENCES

1) Clinical and Laboratory Standards Institute. *Training and Competence Assessment; Approved Guideline*. 3rd ed. CLSI Document QMS03-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.
2) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827
3) Nguyen AND, *et al*. A web-based teaching program for laboratory diagnosis of coagulation disorders. *Arch Pathol Lab Med.* 2000;124:588-593

*****REVISED** 08/21/2017***

GEN.54400 Personnel Records **Phase II**

Personnel records are maintained (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 (e.g. phlebotomists, specimen processors), 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 (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 (e.g. 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). 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 (i.e. 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

REFERENCES

1) Clinical and Laboratory Standards Institute. *Training and Competence Assessment; Approved Guideline*. 3rd ed. CLSI Document QMS03-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.

2) Clinical and Laboratory Standards Institute. *Laboratory Personnel Management, 1st ed.* CLSI guideline QMS16-ED1. Clinical and Laboratory Standards Institute, Wayne, PA; 2015.

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

All testing personnel meet the following requirements.

1. **Personnel performing high complexity testing must have a minimum of one of the following:**
   - **Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; or**
   - **Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489 (see NOTE 2); or**
   - **Meet other provisions defined in 42CFR493.1489(b)(2)(B)(4) or 42CFR493.1489(b)(2)(B)(5)(i) for personnel performing high complexity testing on or before April 24. 1995 (refer to the CLIA regulations for more details)**
2. **Personnel performing moderate complexity testing, including non-laboratory personnel, must have a minimum of one of the following:**
   - **Associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; or**

- **High school graduate or equivalent and have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist; or**
- **High school diploma or equivalent and have a record of training defined in the CLIA regulation 42CFR493.1423 (see NOTE 4)**

NOTE 1: Laboratory and non-laboratory (e.g. 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 maintained in the personnel file to demonstrate compliance. Additional information for assessing personnel qualifications is available at the following link: CAP Personnel Requirements by Testing Complexity.

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

- *60 semester hours or equivalent from an accredited institution that, at a minimum, includes either 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination; AND*
- *Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLS, or other organization approved by HHS (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 (CCLM) as an MLT or MT/MLS; OR*
- *Successfully completed an official U.S. 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 patient test results, including the performance of quality control prior to reporting patient results.*

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

NOTE 6: If more stringent state or local regulations are in place for personnel qualifications, including requirements for state licensure, they must be followed.

Evidence of Compliance:

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 1992(Feb 28):7175 [42CFR493.1423], 7183 [42CFR493.1489]
2) Clinical and Laboratory Standards Institute. *Training and Competence Assessment; Approved Guideline. 3rd ed*. CLSI document QMS03-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.

GEN.55400 Visual Color Discrimination **Phase I**

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

***REVISED** 08/21/2017*
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 testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance. The records must cover all testing performed by each individual.

Training records must be maintained 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.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Training and Competence Assessment; Approved Guideline*. 3rd ed. CLSI Document QMS03-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2009.
2) Clinical and Laboratory Standards Institute (CLSI). *Establishing Molecular Testing in Clinical Laboratory Environments*: CLSI document MM19-A. Clinical and Laboratory Standards Institute, Wayne, PA, 2011.

***NEW** 08/21/2017*
GEN.55499 Competency Assessment - Waived Testing **Phase II**

The competency of personnel performing waived testing is assessed at the required frequency.

NOTE: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450. After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of competency must occur when problems are identified with an individual's performance.

Records of competency assessment may be maintained 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, it is not necessary to assess all six elements listed below at each assessment event. The POCT program may select which elements to assess. 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, as applicable*
5. *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and*
6. *Evaluation of problem-solving skills*

If more stringent state or local regulations are in place for competency assessment of waived testing, they must be followed.

Evidence of Compliance:

- ✓ Written procedure defining the method and frequency for assessing competency **AND**
- ✓ Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required frequency

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1):101053 [42CFR493.1411] and 2003(Oct 1) 1053-54 [42CFR493.1413]
2) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med.* 2000;124:190-191
3) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202
4) Kost GJ. Preventing medical errors in point-of-care testing. *Arch Pathol Lab Med*. 2001;125:1307-1315.
5) Deobald GR, et al. Two approaches to competency assessment for point of care testing. *Clin Chem.* 2001;47(suppl):A187.

*****REVISED** 08/21/2017***

GEN.55500 Competency Assessment - 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: Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450.

Competency must be assessed at the following frequency:

- *During the first year of an individual's duties, competency must be assessed at least semiannually;*
- *After an individual has performed his/her duties for one year, competency must be assessed at least annually;*
- *Retraining and reassessment of competency must also occur when problems are identified with an individual's performance.*

Records of competency assessment may be maintained 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.

Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an elementy is not applicable to the test system. 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 samples or external proficiency testing samples; and*
6. *Evaluation of problem-solving skills*

The laboratory must identify the test systems that testing personnel use to generate patient test results. 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 and can include reagents, components, equipment 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. In many situations, tests performed on the same analyzer may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform (e.g. pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure personnel are performing those aspects correctly.

Many of the elements of competency assessment are performed during routine review of personnel throughout the year. Records of these elements, including adherence to laboratory policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed during routine review by an individual qualified to assess competency for the complexity of testing performed, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment during routine review may be recorded using a checklist.

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 **AND**
- ✓ Written procedure defining the method and frequency for assessing competency

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713]
2) Clinical and Laboratory Standards Institute (CLSI) *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI document QMS03-A3 (ISBN 1-56238-531-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA, 2009.
3) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med.* 2000;124:190-191
4) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med.* 2000;124:195-202
5) Church DL, *et al*. Effects of restructuring on the performance of microbiology laboratories in Alberta. *Arch Pathol Lab Med.* 2000;124:357-361
6) Ward-Cook K, *et al*. Medical technologist core job tasks still reign. *Lab Med.* 2000;31:375-379
7) Haun DE, *et al.* Assessing the competence of specimen-processing personnel. *Lab Med.* 2000;31:633-637
8) Schiffgens J, Bush VA. Four-part approach to competency assessment. *Lab Med.* 2001;32:431-435
9) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

*****NEW** 08/21/2017***

GEN.55510 Qualifications of Individuals Assessing Competency **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.

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*
- *Moderate complexity testing: Technical consultant or individual meeting those qualifications*
- *Waived testing: May be determined by the laboratory director*

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:

- ✓ Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform competency assessment **AND**
- ✓ Records of competency assessments performed by qualified individuals

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713].
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

***REVISED** 08/21/2017*

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

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

NOTE: All responsibilities of section directors (as technical supervisors in laboratories performing high complexity testing) and technical consultants (in laboratories performing moderate complexity testing, but not high complexity testing) must be delegated by the laboratory director in writing. Unsatisfactory performance must be addressed in a corrective action plan.

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

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

Evidence of Compliance:

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

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Oct 1): [42CFR493.1235], [42CFR493.1407(b)], [42CFR493.1445(b)]
2) Clinical and Laboratory Standards Institute (CLSI) *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI document QMS03-A3 (ISBN 1-56238-531-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087-1898 USA, 2009.
3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Brochure #10. What Do I Need to Do to Assess Personnel Competency. November 2012. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

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
- ✓ Written procedure for competency assessment corrective action

PHYSICAL FACILITIES

Inspector Instructions:

	• All Sections, including technical work areas, administrative space, storage areas, patient phlebotomy areas, etc. (adequate space, acceptable temperature/humidity, areas clean, adequate storage areas, adequate emergency power)
	• Is the work area sufficient for you to perform your duties safely and accurately?

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.60000 Adequate Space **Phase II**

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

REFERENCES

1) Koenig AS. Medical laboratory planning and design. Northfield, IL: College of American Pathologists, 1992
2) Guidelines for construction and equipment for hospital and medical facilities. Washington, DC: American Institute of Architects Press, 1993
3) Cooper EC. Laboratory design handbook. London: CRC Press, 1994
4) Mortland KK, Reddick JH. Laboratory design for today's technologies and marketplace. *Lab Med.* 1997;28:332-336
5) Clinical and Laboratory Standards Institute. *Laboratory Design;* 3rd ed. CLSI guideline QMS04-ED3. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
6) Mortland KK, Mortland DB. Lessons learned in lab renovation. *Advance/Lab.* 1999;8(6):92-98
7) Hazlett SO. Perspectives in pathology. The newly designed morgue. *Advance/Lab.* 2000;9(1):10-11
8) Mortland KK, Mortland DB. Lab design: an architect's perspective. *Advance/Lab.* 2000;9(8):49-52

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**

GEN.61300 Climate Control **Phase I**

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

Evidence of Compliance:

- ✓ Temperature and humidity records, if specific ranges are required for instrument and/or reagent use

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 implements a procedure for effective "hand-off" communication.

NOTE: The laboratory must have a procedure 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.

REFERENCES

1) Chapman J. Saving money with computerized materials management. *Advance/Lab.* 1999:8(9):16-18

GEN.62000 Intralaboratory Storage **Phase I**

The intralaboratory storage area is sufficient and free of clutter.

***NEW** 08/21/2017*

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 (e.g. 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 I**

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.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1252(b)(4)]

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 (i.e. state and local fire codes), the regulations of the Authority Having Jurisdiction take precedence.

SAFETY POLICIES, PROCEDURES, AND RECORDS

Inspector Instructions:

	• Sampling of safety policies and procedures
	• Adequate emergency lighting
	• How are your laboratory's safe work practices reviewed? • Is there a specific example of an occupational injury or illness that required medical treatment? What steps were taken to address the incident?
	• For any occupational injury or illness that required medical treatment, further evaluate laboratory leadership's responses, corrective actions, follow-up procedures, and additional measures taken to ensure safety in the workplace

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

The laboratory director or designee reviews and approves all changes to the safety policies and procedures before implementation.

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

There are records for the training of all personnel in safety policies and procedures.

NOTE: A system to ensure that all personnel have read the policies and procedures is required and must form a portion of the orientation program for new personnel. Posting of specific warnings or hazards as appropriate is urged.

Evidence of Compliance:

✓ Records of personnel review of safety policies and procedures

REFERENCES

1) Montgomery L. Health and safety guidelines for the laboratory. Chicago, IL: American Society of Clinical Pathologists Press, 1995
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
3) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827

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

There are records of periodic review (at least annually) of safe work practices to reduce hazards.

NOTE: Review must include bloodborne hazard control and chemical hygiene. If the review identifies a problem, the laboratory must investigate the cause and consider if modifications are needed to the safety policies and procedures to prevent reoccurrence of the problem or mitigate potential risk.

Evidence of Compliance:

✓ Safety committee minutes **OR** records of regular safety inspections **OR** incident reports and statistics **OR** another method defined by the laboratory director

GEN.73500 Lab Accidents **Phase II**

There are written policies and procedures for the reporting and recording of all laboratory accidents resulting in property damage or involving spillage of hazardous substances.

GEN.73600 Occupational Injuries **Phase II**

There are written policies and procedures for the reporting of 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.

REFERENCES

1) Occupational Safety and Health Administration. Improve Tracking of Workplace Injuries and Illnesses; Final Rule, *Fed Register*. Vol. 81, No. 93, 29CRF Part 1904 and 1902. May 12, 2016.

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

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

Evidence of Compliance:

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

*****REVISED** 08/21/2017***

GEN.73800 Emergency Preparedness **Phase II**

There are written policies and procedures defining the role and responsibilities of the laboratory in emergency preparedness for harmful or destructive events or disasters.

NOTE: The specific elements to be included in the emergency preparedness 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. 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 (e.g. HVAC, water, communication, computer system), power failures, natural disasters (e.g. tornado, hurricane, earthquake, fire, flood), emerging public health threats, cyber-attacks, terrorist events, or workplace violence.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Planning for Laboratory Operations During a Disaster; Approved Guideline.* CLSI document GP36-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.
2) Department of Health and Human Services. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; final rule. *Fed Register.* 2016(Sept 16).

GEN.73900 Evacuation Plan **Phase II**

There is a written comprehensive and workable evacuation plan specific for the laboratory.

NOTE: 1. 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). 2. Emergency lighting is adequate for safe evacuation of the laboratory.

REFERENCES
1) Occupational Safety and Health Administration. Exit routes, emergency action plans, and fire prevention plans: standard, 2002 [29CFR1910.38]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

BLOODBORNE PATHOGENS

Inspector Instructions:

	• Sampling of safety policies and procedures • Sampling of records of hepatitis B vaccination or records declining the vaccination • Sampling of personnel safety training records
	• PPE usage
	• What has your laboratory done to reduce or eliminate exposure to bloodborne pathogens during phlebotomy and laboratory testing?

***REVISED** 08/21/2017*
GEN.74000 Bloodborne Pathogens **Phase II**

The laboratory has written policies and procedures for infection control that comply with national, state, and local guidelines on occupational exposure to bloodborne pathogens and to the institution's exposure control plan.

NOTE: Universal or standard precautions must be used when handling all blood and body fluid specimens. 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:

- ✓ Safety manual **AND**
- ✓ Records of universal precaution training for all personnel expected to have contact with body fluids

REFERENCES

1) Ipolito G. The risk of occupational human immunodeficiency virus infection in health care workers. *Arch Intern Med.* 1993;153:1451-1458
2) Howanitz PJ, Schifman RB. Safety practices and infectious risks for laboratory phlebotomists. *Am J Clin Pathol.* 1994;102:553
3) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827
4) The Hospital Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention, Public Health Service. Guidelines for isolation precautions in hospitals. Part II. Recommendations for isolation precautions in hospitals. February 1996
5) McGovern PM, *et al*. Laboratory professionals' compliance with universal precautions. *Lab Med.* 1997;28:725-730
6) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
7) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014

*****REVISED** 08/21/2017***

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 in which blood and body substances are handled and in circumstances during which exposure is likely to occur.

NOTE: 1. Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious materials to pass through to the skin or reach work clothes, skin, footwear, etc. In addition to fluid-resistant gowns, aprons may be required if exposure to large volumes of body fluids is anticipated. 2. 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. 3. PPE is made available to laboratory visitors, as applicable.

REFERENCES

1) Centers for Disease Control. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR.* 1989:38(suppl S-6):1-37
2) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827
3) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
4) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med.* 1999;30:710
5) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline,* 4th ed. CLSI document M29-A4 Clinical and Laboratory Standards Institute, Wayne, PA, 2014.
6) Food and Drug Administration. Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove; final rule, *Fed Register.* 2017 (Jan 18): 81 FR 91722.

*****REVISED** 08/17/2016***

GEN.74200 PPE Instruction **Phase II**

Personnel are instructed in the proper use of personal protective clothing/equipment (*e.g.* gloves, gowns, masks, eye protectors, footwear) and records are maintained.

NOTE: The required elements of training in the use of gloves include (a) Proper fitting of gloves; (b) Replacing gloves immediately when torn or contaminated; (c) Not washing or disinfecting gloves for reuse; (d) Using hypoallergenic gloves when indicated by patient or health care provider history; (e) Decontamination of hands after glove removal using an effective antimicrobial method.

Evidence of Compliance:

- ✓ Written policy for the use of PPE for specific tasks **AND**
- ✓ Records of PPE training

REFERENCES

1) Murray RL. Keep wearing your gloves. *Med Lab Observ.* 1994(Mar):80
2) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827
3) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med.* 1999;30:710
4) Rego A, Roley L. In-use barrier integrity of gloves: latex and nitrile superior to vinyl. *Am J Infect Control.* 1999;27:405-410
5) Department of Labor, Occupational Safety and Health Administration, Occupational Safety and Health Standards. Bloodborne pathogens. *Fed Register.* 2002(July 1): [29CFR1910.1030(d)(3)(i)]
6) Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51.
7) World Health Organization. WHO Guidelines on Hand Hygiene in Health-Care, 2009. http://apps.who.int/iris/bitstream/10665/44102/1/9789241597906_eng.pdf, accessed 12/5/2015.

*****NEW** 08/17/2016***

GEN.74250 Hand Cleaning — Phase II

All personnel remove gloves and clean hands using an effective antimicrobial method after manipulating biological samples or after each patient contact.

REFERENCES

1) Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51.
2) World Health Organization. WHO Guidelines on Hand Hygiene in Health-Care, 2009. http://apps.who.int/iris/bitstream/10665/44102/1/9789241597906_eng.pdf, accessed 12/5/2015.

GEN.74300 Manual Manipulation of Needles — Phase II

There is a written policy that 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.

REFERENCES

1) Jagger J, *et al*. Rates of needlestick injury caused by various devices. *New Engl J Med.* 1988;319:284-288
2) Whitby M, *et al*. Needlestick injury: impact of a recapping device and an associated education program. *Infect Control Hosp Epidemiol.* 1991;12:220-225
3) Bush VJ, *et al*. Advancements in blood collection devices. *Lab Med.* 1998;29:616-622
4) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
5) Charney E. Retractable safety syringe activation study. *J Healthcare Safety Compliance Infect Control.* 1998;2(9):413-415
6) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
7) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014

GEN.74400 Eating/Mouth Pipetting — Phase II

There is a written policy that prohibits smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.74500 Specimen Transport Procedures — Phase II

There are written procedures for the procurement, transportation, and handling of patient specimens (e.g. blood, body fluids, tissue) to ensure that all specimens are submitted in an appropriately labeled and well-constructed container with a secure lid 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.

REFERENCES
1) Centers for Disease Control and Prevention. Evaluation of safety devices for preventing percutaneous injuries during phlebotomy procedures. *MMWR.* 1997;46(2):1
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.74600 Spill Handling — Phase II

There are written procedures for handling spills of blood and other body fluids.

GEN.74700 Hepatitis B Vaccinations — Phase II

Personnel reasonably expected to have direct contact with body fluids are identified and offered hepatitis B vaccinations free of charge.

Evidence of Compliance:

✓ Written policy offering the hepatitis B vaccination to personnel

REFERENCES
1) Centers for Disease Control. Protection against viral hepatitis: recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR.* 1990;39:#RR-2
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.74800 Viral Exposure — Phase II

There is a policy 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

REFERENCES
1) Alpert LI. Managing needlestick accidents in the lab. Northfield, IL: College of American Pathologists CAP Today 1991(Jun);5(6):49
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
3) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
4) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]4)
5) Tarapchak P. Taking care of 'risky' business. *Advance/Lab.* 1999:8(7):69-73
6) Shen C, *et al*. Risk of needle stick and sharp object injuries among medical students. *Am J Infect Control.* 1999;27:435-437
7) Bryce EA, *et al*. Sharps injuries: defining prevention priorities. *Am J Infect Control.* 1999;27:447-455

OTHER INFECTIOUS HAZARDS

Inspector Instructions:

- Sampling of safety policies and procedures
- Sampling of sterilizing device monitoring records

***REVISED** 08/21/2017*

GEN.74900 TB Exposure Plan **Phase II**

The laboratory has a written tuberculosis exposure control plan.

NOTE: This requirement does not apply to laboratories that have no patient exposure or do not handle potentially infectious specimens (e.g. MOHS or pathology interpretation only). This plan must include an exposure determination at defined intervals for all personnel who may have occupational exposure to tuberculosis. Additional elements of the plan include engineering and work practice controls for hazardous activities that potentially may aerosolize Mycobacterium tuberculosis. Such activities include the handling of unfixed tissues in surgical pathology or autopsies, and processing specimens in the microbiology section from patients with suspected or confirmed tuberculosis.

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 (PAPRS) equipped with high efficiency particulate air (HEPA) filters. Accurate fit testing is a key component of effective respirator use.

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

REFERENCES
1) Centers for Disease Control and Prevention/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Washington, DC: US government printing office, Feb 2007
2) CDC. Guidelines for preventing transmission of Mycobacterium tuberculosis in health care settings. *Morb Mortal Weekly Reports*. 2005;54(RR17):1-141.

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:

- ✓ Written procedure for monitoring sterilizing devices **AND**
- ✓ Records of monitoring at defined frequency

FIRE PREVENTION AND PROTECTION

Inspector Instructions:

READ	• Sampling of safety policies and procedures • Sampling of fire safety training records • Sampling of fire extinguisher training records
OBSERVE	• Automatic fire extinguisher systems, if required • Two exit access doors, if required • Audible automatic fire detection and alarm system • Fire alarm station • Portable fire extinguishers, where appropriate

GEN.75100 Fire Prevention Policies and Procedures — Phase II

Policies and procedures are written and 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.

REFERENCES
1) Stern A, *et al*. Fire safety in the laboratory: part I. *Lab Med.* 1993;24:275-277
2) Stern A, *et al*. Fire safety in the laboratory: part II. *Lab Med.* 1993;24:350-352
3) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
4) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204

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. 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. An AFE system is always required if there are unattended laboratory operations employing flammable or combustible reagents. "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

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

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.

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

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 (i.e., 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 (*e.g.* personnel roster with dates of participation)

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

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

There is an automatic fire detection and alarm system.

NOTE: 1. 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. 2. The fire alarm is audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms. 3. Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204

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.

REFERENCES
1) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204
2) National Fire Protection Association. NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals, Chapter 6. Quincy, MA: NFPA, 2004
3) National Fire Protection Association Standard 72: National Fire Alarm and Signaling Code, 2013 edition, Chapter 27.6

GEN.75700 Fire Extinguishers **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.

REFERENCES
1) National Fire Protection Association Standard 10: Standard for Portable Fire Extinguishers, 2013 edition
2) Stern A, *et al*. Fire safety in the laboratory. Part I. *Lab Med.* 1993;24:275-277
3) Stern A, *et al*. Fire safety in the laboratory. Part II. *Lab Med.* 1993;24:350-352
4) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204

GEN.75800 Fire Extinguishers **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

REFERENCES
1) Stern A, *et al*. Fire safety in the laboratory: part I. *Lab Med.* 1993;24:275-277
2) Stern A, *et al*. Fire safety in the laboratory: part II. *Lab Med.* 1993;24:350-352
3) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
4) National Fire Protection Association Standard 10: Standard for Portable Fire Extinguishers, 2013 edition
5) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204

ELECTRICAL SAFETY

Inspector Instructions:

- Sampling of electrical grounding records, if applicable

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*
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.

REFERENCES

1) Occupational Safety and Health Administration. Electrical. Use of equipment. US Government Printing Office, 1999(Jul 1): [29CFR1910.334]

CHEMICAL SAFETY

Inspector Instructions:

	• Sampling of chemical safety policies and procedures • Sampling of SDS (formerly MSDS) sheets
	• Flammable and combustible liquids (properly stored) • Acids and bases (properly stored) • Sampling of hazardous chemicals (labeling) • PPE usage

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 **AND**
- ✓ Written procedure for chemical fume hood function verification **AND**
- ✓ Records of testing

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances hazard communication: standard. 2012: [29CFR1910.1200]
2) Occupational Safety and Health Administration. Occupational exposures to hazardous chemicals in laboratories: standard. 2012: [29CFR1910.1450]
3) Karcher RE. Is your chemical hygiene plan OSHA-proof? *Med Lab Observ.* 1993(Jul):29-36
4) Occupational Safety and Health Administration. Occupational exposure to methylene chloride: standard. 1997: [29CFR1910;1915;1926]
5) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med.* 1999;30:710

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.

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances. Hazard communication. Washington, DC: US Government Printing Office, 2007(Jan 1): [29CFR1910.1200]

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.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

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 periodically assess its usability.

REFERENCES

1) Occupational Safety and Health Administration. Hazardous materials. Hazardous waste operations and emergency response. US Government Printing Office, 1999(Jul 1): [29CFR1910.120]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

GEN.76500 Flammable Storage — Phase II

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

NOTE: 1. 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 (e.g. 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 and 20 gallons (75.7 L) inside a safety cabinet and double those numbers if there is an automatic fire suppression system. 2. Safety cans should be used for bulk storage of flammable and combustible liquid (National Fire Protection Association classes I and II). 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. Safety cans should be used instead of glass bottles if the purity required does not mandate glass storage.

REFERENCES

1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

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.

REFERENCES
1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

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.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

COMPRESSED GASES

Inspector Instructions:

- Gas cylinders (properly stored and secured)

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*

REFERENCES
1) National Fire Protection Association Standard 55: Compressed Gases and Cryogenic Fluids Code, 2013 edition

RADIATION SAFETY

Inspector Instructions:

	• Sampling of radiation safety policies and procedures • Sampling of radiation area surveys/wipe tests records • Sampling of radioactive waste disposal records • Sampling of personnel records of radionuclide training
	• Radionuclide storage areas (properly shielded) • Appropriate signage where radioactive materials are used/stored
	• Does your laboratory have representation at radiation safety committee meetings? • How does your laboratory check the effectiveness of workbench decontamination?

NOTE TO INSPECTOR: The following requirement applies to laboratories that do not perform anatomic pathology on-site, and for whom the Anatomic Pathology checklist is not used.

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

There are specific policies and procedures for the safe handling of tissues that may contain radioactive material (*e.g.* sentinel lymph nodes, breast biopsies, prostate "seeds", *etc.*).

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

REFERENCES

1) Glass EC, *et al*. Editorial: radiation safety considerations for sentinel node techniques. *Ann Surg Oncol.* 1999:6:10
2) Miner TJ, *et al*. Guideline for the safe use of radioactive materials during localization and resection of sentinel lymph nodes. *Ann Surg Oncol.* 1999;6:75-82
3) Cibull ML. Handling sentinel lymph node biopsy specimens. A work in progress. *Arch Pathol Lab Med*. 1999;123:620-621
4) Pfeifer JD. Sentinel lymph node biopsy. *Am J Clin Pathol.* 1999;112:599-602
5) Barnes CA. False-negative frozen section results. *Am J Clin Pathol.* 2000;113:900
6) Fitzgibbons PL, *et al*. Recommendations for handling radioactive specimens obtained by sentinel lymphadenectomy. *Am J Surg Pathol.* 2000;24:1549-1551

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

GEN.77110 Radiation Safety Manual **Phase II**

There is an up-to-date radiation safety manual that includes sections on decontamination and radioactive waste.

NOTE: A radiation safety manual providing procedures for the safe handling of radiation substances in both routine and emergency situations is required by the Nuclear Regulatory Commission (NRC). Requirements for laboratory safety in nuclear medicine can be found in several references.

REFERENCES
1) U.S. Nuclear Regulatory Commission Guide for the preparation of applications for medical use programs. Regulatory guide 10.8: Appendix H model procedure for area surveys. Washington, DC: USNRC, 1987.
2) Clinical and Laboratory Standards Institute. *Clinical Laboratory Waste Management; Approved Guideline*. 3rd ed. CLSI document GP05-A3. CLSI, Wayne, PA, 2011.

***NEW** 08/21/2017*

GEN.77115 Workspace Decontamination **Phase II**

Workbenches and sinks are decontaminated each day of use, and the effectiveness tested at least monthly

NOTE: If the laboratory uses only Iodine-125 either a wipe test or a portable scintillation probe can be used.

Evidence of Compliance:

- ✓ Records of daily workbench/sink decontamination **AND**
- ✓ Records of monthly effectiveness tests

REFERENCES
1) U.S. Nuclear Regulatory Commission Guide for the preparation of applications for medical use programs. Regulatory guide 10.8: Appendix H model procedure for area surveys. Washington, DC: USNRC, 1987.

***NEW** 08/21/2017*

GEN.77120 Radionuclides Handling **Phase II**

There are written policies regarding authorization or restriction of personnel handling radionuclides.

NOTE: These policies should be incorporated into the department's radiation safety manual.

***NEW** 08/21/2017*

GEN.77125 Radionuclide Leak **Phase II**

There are written procedures for notification if a damaged or leaking radionuclide shipment is received.

NOTE: Procedures must include inspection, monitoring of shipments, and instructions for notification, if leakage or damage is noted in a radionuclide shipment.

Evidence of Compliance:

- ✓ Records of inspections and notifications

REFERENCES
1) Clinical and Laboratory Standards Institute. *Clinical Laboratory Safety; Approved Guideline.* 3rd ed. CLSI document GP17-A3. Clinical and Laboratory Standards Institute, Wayne, PA, 2012.
2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication, emergency response information and training requirements. *Fed Register.* 2003(Oct 1): [49CFR172.403, 600, 602, 604].

***NEW** 08/21/2017*

GEN.77130 Radionuclide Storage **Phase II**

Radionuclide storage and decay areas are properly shielded, if required for specific isotopic materials.

NOTE: Radionuclide storage and decay areas must be properly shielded, if required for specific isotopic materials, to avoid excessive exposure to personnel and interference with counting procedures.

Evidence of Compliance:

✓ Written procedure defining shielding requirements for radionuclide storage an decay areas

***NEW** 08/21/2017*

GEN.77135 Radiation Surveys **Phase II**

There are regular radiation area surveys and wipe tests, with records maintained.

NOTE: Routine radiation surveys and wipe tests to determine exposure rates and detect contamination must be performed and recorded at defined frequency.

Evidence of Compliance:

✓ Written procedure defining frequency of radiation survey and wipe tests to determine exposure rates and detect contamination

***NEW** 08/21/2017*

GEN.77140 Radioactive Material Sign **Phase I**

All areas or rooms where radioactive materials are being used or stored are posted to indicate the presence of radioactive materials.

NOTE: For US laboratories, all areas or rooms where radioactive materials are being used or stored must be posted to indicate the presence of radioactive materials, consistent with 10CFR20, Appendix C.

REFERENCES

1) Nuclear Regulatory Commission; Standards for Protection Against Radiation. *Fed Register*. 2004(Jan 1):354-421[10CFR20.2402].

***NEW** 08/21/2017*

GEN.77145 Radionuclide Training **Phase II**

Personnel receive training in decontamination routines and in the safe handling and proper disposal of radionuclides (wastes, syringes, needles, and sponges) with records maintained.

Evidence of Compliance:

✓ Records of radionuclide training in personnel file

***NEW** 08/21/2017*

GEN.77150 Radioactive Waste **Phase II**

Radioactive waste is stored separately, under required conditions, and appropriately discarded, with records maintained.

NOTE: Records of the radioactive trash disposal must be maintained. For US laboratories, NRC regulations specify that separate areas be established for the receipt of radioactive waste and that these areas be properly shielded to reduce radiation levels below those maximum permissible limits specified in 10CFR20.

Evidence of Compliance:

✓ Written procedure defining criteria for proper storage and disposal of radioactive waste

REFERENCES

1) Clinical and Laboratory Standards Institute. *Clinical Laboratory Waste Management; Approved Guideline*. 3rd ed. CLSI document GP05-A3. CLSI, Wayne, PA, 2011.

***NEW** 08/21/2017*

GEN.77155 Safety Committee Representation **Phase II**

There are records indicating that a laboratory representative is a member of and/or attends institutional radiation safety committee meetings regularly.

NOTE: Independent laboratories must have a radiation safety officer who fulfills the functions of an institutional radiation safety committee.

Evidence of Compliance:

✓ Records of laboratory participation in institutional Safety Committee meeting **OR** participation in other appropriate group responsible for radiation safety

ENVIRONMENTAL SAFETY

Inspector Instructions:

	• Ergonomic evaluation
	• Emergency eyewash available and tested properly
	• How does your laboratory prevent workplace-related musculoskeletal disorders?

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 (e.g. 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

REFERENCES
1) Gile TJ. Ergonomics in the laboratory. *Lab Med*. 2001;32:263-267
2) U.S. Dept. of Labor, Occupational Safety and Health Administration. Ergonomic safety and health program management guideline. 54 *Fed Register* 3904 (1989), modified at 29CFR1910)

GEN.77300 Excessive Noise **Phase II**

The laboratory has a policy to protect 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).

REFERENCES
1) U. S. Department of Labor, Occupational Safety & Health Administration: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9735&p_table=STANDARDS

***REVISED** 08/21/2017*

GEN.77400 Emergency Eyewash **Phase II**

The laboratory has adequate plumbed or self-contained emergency eyewash facilities 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 maintained.

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.

Immediate and prolonged (15 minutes) flushing is generally necessary for corrosive/alkali agents. 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 travel distance from areas in the laboratory where hazardous chemicals are present*
2. *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 15°C and 37°C (60°F and 100°F). Actual temperature recording is not required.)*
5. *Plumbed systems are activated weekly*
6. *Self-contained units are visually examined weekly*

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*

For self-contained eyewash facilities, the manufacturer's specifications should be available for review by an inspector. The availability of disposable eyewash bottles in the work area does not replace the need for an eyewash facility in areas at risk for eye exposure from corrosive chemicals.

REFERENCES
1) American National Standards Institute. Emergency eyewash and shower equipment. New York, NY: ANSI, 20049;Z358.1
2) Occupational Safety and Health Administration. Medical and first aid. Medical services and first aid. US Government Printing Office, 1998(June 18):[29CFR1910.151(c)]

OTHER HAZARDS

Inspector Instructions:

	• Sampling of safety policies and procedures
	• UV light signage

GEN.77500 Liquid Nitrogen **Phase II**

Adequate policies, procedures, and practices are in place for the use of liquid nitrogen.

NOTE: Practices for the safe handling of liquid nitrogen include:

1. *The mandatory use of appropriate gloves, shielding of all skin and the use of a face shield when decanting or entering an open container of LN*
2. *Storage and use of all containers of LN only in well-ventilated areas*
3. *Availability of a Safety Data Sheet*

REFERENCES
1) OSHA Quick Facts: Laboratory Safety Cryogens and Dry Ice. Occupational Safety and Health Administration Website. https://www.osha.gov/Publications/laboratory/OSHAquickfacts-lab-safety-cryogens-dryice.pdf. Reviewed October 2011. Accessed 11/24/2015.

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

There are 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, 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

REFERENCES
1) Fleming DO, *et al.* Laboratory safety. Principles and practices, 2nd ed. Washington, DC: American Society for Microbiology, 1995

GEN.77700 Latex Allergy **Phase II**

The laboratory has a written program 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

REFERENCES

1) Bauer X, *et al*. Health risk in hospitals through airborne allergens for patients pre-sensitized to latex. *Lancet.* 1993;342:1148-1149
2) Yassin ME, *et al*. Latex allergy in hospital employees. *Ann Allergy.* 1994;72:245-249
3) Tomazic VJ, *et al*. Cornstarch powder on latex products is an allergen carrier. *J Allergy Clin Immunol.* 1994;93:751-758
4) Yunginger JW, *et al*. Extractable latex allergens and proteins in disposable medical gloves and other rubber products. *J Allergy Clin Immunol.* 1994;93:836-842
5) Mendyka BE, *et al*. Latex hypersensitivity: an iatrogenic and occupational risk. *Am J Crit Care.* 1994;3:198-201
6) Valentino VM, *et al*. Latex-induced asthma in four healthcare workers in a regional hospital. *Occup Med.* 1994;44:161-164
7) Tarlo SM, *et al*. Control of airborne latex by use of powder-free latex gloves. *J Allergy Clin Immunol.* 1994;93:985-989
8) Personius CD. Patients, health care workers, and latex allergy. *Med Lab Observ.* 1995;27(3):30-32
9) Vandenplas O, *et al*. Latex gloves with a lower protein content reduce bronchial reactions in subjects with occupational asthma caused by latex. *Am J Respir Crit Care Med.* 1995;151:887-891
10) Thomson CM. The potential risks of latex. *Brit Med J.* 1996;6(5):12-14
11) Ownby DR, *et al*. The prevalence of anti-latex IgE antibodies in 1000 volunteer blood donors. *J Allergy Clin Immunol.* 1996;97:1188-1192
12) Kaczmarek RG, *et al*. Prevalence of latex-specific IgE antibodies in hospital personnel. *Allergy Asthma Immunol.* 1996;76:51-56
13) Liss GM, *et al*. Latex allergy: epidemiological study of 1351 hospital workers. *Occup Environ Med.* 1997;54:335-342
14) Leung R, *et al*. Prevalence of latex allergy in hospital staff in Hong Kong. *Clin Exp Allergy.* 1997;27:167-174
15) The National Institute for Occupational Safety and Health (NIOSH). Alert. Preventing allergic reactions to natural rubber latex in the workplace. Washington, DC: DHHS publication 97-135, Jun 1997
16) Sussman GL, *et al*. Incidence of latex sensitization among latex glove users. *J Allergy Clin Immunol.* 1998;101:171-178
17) Sainato D. The irritation of latex allergy. Labs should be aware of causes and solutions. *Clin Chem News.* 1999;25(7):1-10
18) Graves PB. Latex allergy: a laboratory view. *Amer Clin Lab.* 2000;19(2):16-17
19) Carroll P, Celia F. What you need to know about latex allergy. *Med Lab Observ.* 2000;32(7):64-66

WASTE DISPOSAL

Inspector Instructions:

READ	• Sampling of waste disposal policies and procedures
ASK	• How does your laboratory dispose of sharps? • How does your laboratory dispose of hazardous chemicals?

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

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

NOTE: 1. The laboratory is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition. 2. The method for the disposal of all solid and liquid wastes is in compliance with local, state and federal 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

REFERENCES

1) Ornelas D, *et al*. The laboratory's role in reducing hazardous waste. *Lab Med.* 1998;29:287-290
2) Ornelas D, *et al*. The role of recycling and chemical substitution in pollution prevention programs. *Lab Med.* 1998;29:356-359
3) Reinhart DR, McCreanor PT. Medical waste management: where does the solid waste go? *Lab Med.* 2000;31:141-145
4) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

GEN.77900 Biohazard Disposal Containers — Phase II

All infectious wastes (*e.g.* 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.

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

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.

REFERENCES

1) Bush VJ, *et al*. Advancements in blood collection devices. *Lab Med.* 1998;29:616-622
2) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
3) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
4) Occupational Safety and Health Administration. Enforcement procedures for the occupational exposure to bloodborne pathogens. Washington, DC: U.S. Government Printing Office, OSHA Directive CPL 2-2.44D, 1999 (Nov 5)
5) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

LABORATORIES WITH CALIFORNIA LABORATORY LICENSURE

This section contains requirements that are unique to California Clinical Laboratory Laws defined in the California Business and Professions Code (BPC) and the California Code of Regulations (CCR). California law applies to facilities that provide analyses of all body specimens, including blood, urine, feces, hair, breath,

saliva, and body fluids on specimens originating from the state of California. Laboratories with clinical laboratory licensure or registration from the state of California must be in compliance with these requirements, as well as other applicable CAP checklist requirements (e.g. personnel, specimen collection, results reporting). If there are differences between the requirements in this section and other sections, the laboratory must follow whichever is most stringent.

Laboratories with a California laboratory license located in other states must be in compliance with these requirements for the portion of testing performed on specimens that originate from California.

This section does not apply to the following types of laboratories, which are exempt from California laboratory law:

- *Laboratories owned by the US government*
- *Public health laboratories*
- *Forensic laboratories*
- *Research and teaching laboratories that do not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of the health of individual patients*

Inspector Instructions:

	• Sampling of personnel policies and procedures • Records of personnel qualifications • Job descriptions
	• Posting of state clinical laboratory license • Posting of laboratory personnel licenses and registration • Patient reports for laboratory director name
	• How is supervision of unlicensed personnel and trainees performed?

*****NEW** 08/21/2017***

GEN.78200 Laboratory Director Licensure **Phase II**

Laboratory directors listed on the state clinical laboratory license or registration have appropriate California licensure as a physician, doctoral scientist, or doctoral-level bioanalyst.

NOTE: If a licensed doctoral scientist (e.g. clinical chemist, clinical microbiologist, or clinical toxicologist) is listed as a laboratory director, the scope of testing performed under the individual's direction must be limited to his or her specialty. If a licensed doctoral-level bioanalyst is listed as a laboratory director, the scope of testing performed under the individual's direction may include all specialty areas of the clinical laboratory.

Directors of laboratories located outside of the state of California with a California Clinical Laboratory License must meet qualifications equivalent to those required for licensure.

The individual designated as the laboratory director for CAP accreditation must also meet the CAP's laboratory director qualifications and responsibilities defined in the Director Assessment Checklist. If there is more than one laboratory director listed on the California laboratory license, one laboratory director from the California license must be designated as the laboratory director for CAP accreditation.

REFERENCES
1) California BPC §1209(a)
2) California BPC §1264

*****NEW** 08/21/2017***

GEN.78225 Laboratory Director - Acute Care Hospital **Phase II**

Laboratories located in a general acute care hospital are directed by a qualified pathologist. If a qualified pathologist is not available, a licensed non-pathologist physician or licensed bioanalyst qualified as a laboratory director (refer to TLC.10100) may direct the laboratory; however, a qualified pathologist must be available.

NOTE: A qualified pathologist is defined as being board certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic board of Pathology.

Blood gas laboratories with testing limited to blood gas and/or electrolyte analysis located at acute care hospitals where there is a clinical laboratory may be directed by a licensed non-pathologist physician qualified as a laboratory director.

REFERENCES
1) California BPC §1209(f)

*****NEW** 08/21/2017***

GEN.78250 Personnel Qualifications and Licensure **Phase II**

Laboratory supervisors and testing personnel meet the qualifications defined in California state law, including personnel licensure where required, and perform duties appropriate to the scope of their licenses.

NOTE: The table below includes a summary of the qualifications for each laboratory role based on the California Business and Professions Code (BPC) and the California Code of Regulations (CCR). Laboratory results must be reviewed and released by licensed persons, where applicable. It is unlawful to pose as a licensed person when not licensed. Refer to the California Department of Public Health website for additional information and qualifications and licensure.

For laboratories located outside of the state of California with a California clinical laboratory license, personnel must meet the qualifications defined in the table below; however, in lieu of obtaining a California personnel license, the laboratory must retain records demonstrating the equivalence of the individual's qualifications to those required for licensure.

Physician office laboratories (with five or fewer physicians that perform tests only on their own patients) are exempt from personnel licensure requirements, but need to meet the CLIA regulations for the complexity of testing performed. If high complexity testing is performed, the physician must be present on-site when testing is performed.

If there are differences between the qualifications in the table below and other CAP checklist requirements, the laboratory must follow the most stringent requirement.

Role	Qualifications	Code/Regulation

Histocompatibility Laboratory Director	• Licensed physician, doctoral-level bioanalyst, or doctoral scientist **AND** • Four years of experience in immunology, two of which are in histocompatibility testing	BPC §1209.1
Cyto genetics Laboratory Director	• Licensed clinical cytogeneticist, pathologist, or bioanalyst who meets CLIA high complexity laboratory director requirements	17 CCR §1030.6
Genetic Molecular Biology Laboratory Director	• Licensed clinical genetic molecular biologist, pathologist, or bioanalyst who meets CLIA high complexity laboratory director requirements	17 CCR §1030.7
Oral Pathology Laboratory Director	• Board-certified pathologist or a dentist licensed as an oral pathology laboratory director	17 CCR §1030.8
Clinical Consultant	• Individual licensed to direct a clinical laboratory in California or to practice medicine	17 CCR §1036
General Supervisor	• Individual licensed to perform high complexity testing in California or to practice medicine **AND** • Have two years of experience in high-complexity testing in the specialty or specialties supervised NOTE: More stringent requirements for education and/or training of general supervisors are included in the Cytology and Histocompatibility Checklists	17 CCR §1036.1
Technical Consultant - Moderate Complexity Laboratory	• Individual licensed to perform high complexity testing in California or to practice medicine **AND** • Have two years of experience in moderate or high complexity testing in the specialty or specialties supervised	17 CCR §1036.2
Waived Laboratory Supervisor	• Individual qualified as waived testing personnel (see below) that meets all of the following criteria: ❍ Has a Bachelor's degree ❍ Is a licensed health care professional ❍ Has one year of experience in clinical laboratory testing in those tests supervised **AND** ❍ Has competency in the tests supervised	BPC §1206.5(a) 17 CCR §1036.3
Technical Supervisor	• Individual licensed to perform high complexity testing or practice medicine in California **AND** • Have the following years of experience:	17 CCR §1036.4 42CFR493.1449

	○ Physician or doctoral scientists - one year ○ Master's level scientist - two years ○ Bachelor's-level scientist - four years NOTE: More stringent requirements for education and/or training of section directors/technical supervisors are included in the Histocompatibility, Cytogenetics, Transfusion Medicine, Cytopathology, and Molecular Pathology Checklists	
Testing Personnel - High Complexity Testing	• Licensed physician **OR** • Individual licensed to direct a clinical laboratory for testing performed within the specialty/ subspecialty authorized by the license **OR** • Individual licensed to perform high complexity testing with exceptions for persons with military training and experience ○ Individuals with a Clinical Laboratory Scientist Generalist license may perform testing in all complexities and specialties except cytology ○ Individuals with a limited Laboratory Scientist license in a particular specialty may only perform high complexity testing under the scope of their license. Limited specialty licenses include the following: ■ Clinical Chemist Scientist ■ Clinical Cytogeneticist Scientist ■ Clinical Genetic Molecular Biologist Scientist ■ Clinical Hematologist Scientist ■ Clinical Histocompatibility Scientist ■ Clinical Immunohematologist Scientist ■ Clinical Microbiologist Scientist ■ Clinical Toxicologist Scientist • Other authorized individuals as defined in BPC §1206.5(c)	BPC §1206.5(c) BPC §1261 BPC §1210 17 CCR §1031(b)(1-5)

Testing Personnel - Moderate Complexity	• Licensed physician or individual licensed to direct a clinical laboratory **OR** • Individual licensed to perform high complexity testing as a generalist or in any specialty **OR** • Licensed Medical Laboratory Technician (MLT) with the exception of immunohematology procedures and microscopic analysis **OR** • Licensed registered nurses, physician assistants, respiratory care practitioners, and perfusionists, and other authorized individuals as defined in BPC §1206.5(b)	BPC §1206.5(b) BPC §1210 BPC §1260.3 17 CCR §1032.5
Testing Personnel - Waived Testing	• Licensed physician or individual licensed to direct a clinical laboratory **OR** • Individual licensed to perform high complexity testing as a generalist or in any specialty **OR** • Licensed Medical Laboratory Technician (MLT) **OR** • Licensed registered nurses, physician assistants, perfusionists, certified medical assistants, and other authorized individuals as defined in BPC §1206.5(a)	BPC §1206.5(a) BPC §1210 BPC §1260.3 17 CCR §1032.5
Cytotechnologist	• Licensed cytopathologist **OR** • Licensed cytotechnologist working under a qualified pathologist ○ May perform all cytology tests and procedures on cytology specimens, including, but not limited to, microscopic and non-microscopic methodologies (i.e. molecular-based testing for infectious disease or cancer diagnosis)	BPC §1270

REFERENCES
1) California BPC §1280

***NEW** 08/21/2017*

GEN.78275 Posting of Licenses and Certificates **Phase II**

The clinical laboratory license, laboratory personnel licenses, and phlebotomy certificates are conspicuously posted in the laboratory (original or official duplicate).

NOTE: When performing phlebotomy in areas outside of the laboratory, phlebotomy technicians must carry a current identification card issued from Laboratory Field Services.

REFERENCES
1) California BPC §1266
2) California Code of Regulations, Title 17 §1034

***NEW** 08/21/2017*

GEN.78300 Unlicensed Laboratory Personnel **Phase II**

Unlicensed laboratory personnel that assist with the analytical phase of testing or perform pre- or post-analytical procedures have a minimum of a high school diploma or equivalent and are appropriately trained, supervised, and perform only those duties allowed under California Business and Professions code.

NOTE 1: Unlicensed personnel may not perform laboratory testing in laboratories other than physician office laboratories. Duties that may not be performed by unlicensed personnel include the following examples:

- *Recording of test results (however, may transcribe results that have been previously recorded, automatically by a testing instrument or manually by a physician or licensed individual)*
- *Performance of any test or part thereof that involves the quantitative measurement of the specimen, or test reagent, or any mathematical calculation to determine the results or the validity of a test procedure*
- *Performance of any phase of testing in the specialty of immunohematology beyond the initial collection and centrifugation*
- *Standardization or calibration of instruments or assessment of instrument performance by monitoring results of standards and controls*
- *Quantitative measurement of any sample or reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers*

NOTE 2: Unlicensed personnel may perform the following types of pre- and post-analytical activities under the "supervision and control" of a physician or appropriately licensed individual: specimen labeling, handling, preservation or fixation, processing or preparation, transportation, and storing of specimens. Supervision and control requires the individual supervising the activity to be either physically present in the laboratory or available by telephone or other electronic means.

NOTE 3: Unlicensed personnel may assist with activities in the analytical phase under "direct and constant supervision" by a physician or appropriately licensed individual. Direct and constant supervision requires personal observation and critical evaluation of the activities performed by unlicensed personnel by a physician or licensed person during the entire time of those activities. The activities may include the following:

- *Assist a licensed physician and surgeon or personnel licensed under the Business and Professions code Chapter 3 Clinical Laboratory Technology (BPC §1242), other than a trainee*
- *Assist in preventive maintenance and troubleshooting*
- *Prepare and store reagents and culture media*
- *Assist in the performance of quality control procedures*
- *In the case of qualitative and semi-quantitative "spot, tablet, or stick" tests, add the test reagent to the specimen or vice versa (the results must be read by licensed personnel)*
- *In the case of microbiological tests, make primary inoculation of test material onto appropriate culture media, stain slide preparations for microscopic examination, and subculture from liquid media*

REFERENCES

1) California BPC §1206(a)
2) California BPC §1206.5
3) California BPC §1212
4) California BPC §1269

***NEW** 08/21/2017*

GEN.78325 Laboratory Owners **Phase II**

All laboratory owners are listed on the state clinical laboratory license.

NOTE: Anyone with a 5% or more interest in a laboratory is considered an owner. The laboratory owner is considered jointly and severally responsible with the laboratory director for the laboratory.

REFERENCES
1) California BPC §1211
2) California BPC §1265(b)

*****NEW** 08/21/2017***

GEN.78350 Phlebotomist Qualifications and Duties **Phase II**

Phlebotomy is performed by qualified licensed or certified personnel. Duties performed are limited to the scope of practice for phlebotomy technicians as defined in California law.

NOTE: Phlebotomy may be performed by individuals qualified as one of the following:
- *Licensed physician*
- *Individual licensed under the Business and Professions Code Chapter 3 Clinical Laboratory Technology (BPC §1242)*
- *Licensed registered nurse, vocational nurse, respiratory care practitioner, naturopathic doctors, certified medical assistants, or other licensed individual as defined in California law.*
- *Licensed trainee **OR***
- *Certified phlebotomy technician employed by the laboratory*

A licensed trainee may perform arterial puncture, venipuncture, or skin puncture as part of a training program under the "direct and responsible supervision" of a licensed person. Direct and responsible supervision requires personal observation and critical evaluation of the activity of a trainee by a physician or appropriately licensed individual during the entire time that the trainee is performing the activity.

REFERENCES
1) California Code of Regulations, Title 17 §1034
2) California BPC §1242
3) California BPC §1243
4) California BPC §1246

*****NEW** 08/21/2017***

GEN.78375 Training Programs **Phase II**

If the laboratory operates a training program for clinical laboratory personnel, the program is approved by the state of California and follows the state's requirements for supervision of trainees.

NOTE: Trainees must work under the direct and responsible supervision of the laboratory director or a licensed individual other than a licensed trainee. The ratio of licensed laboratory personnel to trainee shall be no less than two licensed individuals to one trainee.

REFERENCES
1) California BPC §1205
2) California BPC §1222.5
3) California BPC §1286
4) California Code of Regulations, Title 17 §1035

*****NEW** 08/21/2017***

GEN.78400 Patient Reports **Phase II**

Patient reports include the name of the laboratory director of the laboratory performing the test.

REFERENCES
1) California Code of Regulations, Title 17 §1055

***NEW** 08/21/2017*

GEN.78425 Specimen Storage Box **Phase II**

There is a written policy for notification of the Department of Consumer Affairs when an unlocked specimen storage box (e.g. secured box located outside a clinic for specimen pick-up) is identified.

REFERENCES
1) California BPC §1220.5

BIOREPOSITORIES

INTRODUCTION

The General Checklist applies to all sections of the biorepository. An inspection of a biorepository section or department will include the Biorepository Checklist.

The requirements in this section only apply to biorepositories enrolled in the Biorepository Accreditation Program.

POLICIES AND PROCEDURES

Inspector Instructions:

READ	• Representative sample of procedures for completeness and biorepository director review. Current practice must match contents of policies and procedures. • Document control policy • Privacy and confidentiality policies and procedures
ASK	• How do you access procedures? • What procedure has most recently been implemented or modified? • How do you ensure all copies of procedures are up to date? • How are changes in procedures recorded and communicated to staff? • How does the facility protect patient information?
DISCOVER	• Identify a newly implemented procedure in the prior two years and follow the steps through authoring, director review and staff training

***NEW** 08/17/2016*

GEN.80000 Procedure Manual **Phase II**

A complete procedure manual is available in a paper-based, electronic, or web-based format at the workbench or in the work area.

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert

accurately and precisely describes the procedure as performed in the biorepository. Any variation from this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly recorded and approved.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- *A complete manual is available for reference*
- *The card file or similar system corresponds to the complete manual and is subject to document control*

NOTE 4: Electronic manuals accessed by computer are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the biorepository as long as the electronic versions are readily available to all personnel and personnel have been trained on how to access them. However, procedure manuals must be available to biorepository personnel when the electronic versions are inaccessible (e.g. during biorepository information system or network downtime); thus, the biorepository must maintain paper copies, electronic copies on CD or other digital media, or have an approved alternative mechanism to access web-based files during network downtimes. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic procedure manuals and electronic copies of procedures are subject to proper document control (see GEN.80600), and there must be records of biennial review. Records of review of electronic procedures may include statements such as "reviewed by [name of reviewer] on [date of review]" in the electronic record. Alternatively, paper review sheets may be used to record review of electronic procedures. Record of review by a secure electronic signature is NOT required.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.

***NEW** 08/17/2016*

GEN.80100 Policy/Procedure - Confidentiality **Phase II**

Policies and procedures are in place to minimize the risk to individuals from whom the specimens and data were obtained and to protect their privacy and confidentiality.

***NEW** 08/17/2016*

GEN.80200 Policy and Procedure Review **Phase II**

There are records of review of all technical policies and procedures by the current director or designee at least every two years.

NOTE: Only technical policies and procedures are addressed in this requirement. Biennial review is not required for other controlled documents.

The director must ensure that the collection of policies and procedures is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the biorepository and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/24 of all policies and procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index is not a sufficient record that each policy or procedure has been carefully reviewed. Signature or initials on each page of a policy or procedure is not required.

***NEW** 08/17/2016*

GEN.80300 New Procedure Review **Phase II**

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

NOTE: Current practice must match the policy and procedure documents.

***NEW** 08/17/2016*

GEN.80400 New Director Procedure Review **Phase II**

If there is a change in directorship of the biorepository, the new director ensures (over a reasonable period of time) that biorepository procedures are well documented and undergo appropriate review.

***NEW** 08/17/2016*

GEN.80500 Knowledge of Policies and Procedures **Phase II**

The biorepository has a defined process and records indicating that all personnel are knowledgeable about the contents of the policies and procedures (including changes) relevant to the scope of their biorepository activities.

NOTE: This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the director.

Evidence of Compliance:

- ✓ Relevant quizzes and results **OR** record confirming competency **AND**
- ✓ Systems to record policy and procedure changes **AND**
- ✓ Records of receipt/training in either paper or electronic format

GEN.80600 Document Control **Phase II**

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

NOTE: The document control system must ensure that only current policies, procedures, and forms are in use.

It may be helpful for some biorepositories to 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 or superseded.

Evidence of Compliance:

- ✓ Electronic documents on a shared file **OR** commercial document system **OR** a biorepository developed organized system

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6 (ISBN 1-56238-869-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 2013.
2) ISO 15189:2003 Medical laboratories -- Particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2003

***NEW** 08/17/2016*

GEN.80700 Discontinued Procedure **Phase II**

When a procedure is discontinued or replaced, a paper or electronic copy is maintained for at least two years, recording initial date of use, and retirement date.

QUALITY MANAGEMENT

The biorepository must have a written quality management program to systematically ensure the quality of services. In biorepositories that are part of a larger institution (e.g. a hospital), the biorepository quality management program may be integrated with the institutional program.

Inspector Instructions:

	• Sampling of QM policies and procedures • Procedure for communication of employee concerns • Sampling of quality indicators with follow-up actions when targets are not achieved • Annual appraisal of effectiveness of the QM Program • Records of instructions/recommendations from IRBs and clients • Records of the selection and evaluation of services
	• CAP sign regarding the reporting of quality concerns
	• How are IRB and client concerns and recommendations addressed? What were the results and what actions were taken as a result of the findings? • Is there a specific example when problems were identified that could have interfered with research result integrity, participant/client care or safety?
	• If any problems are found during review of quality measurements, or when asking questions, further evaluate the biorepository's investigation and resolution, including root cause analysis and associated risk-reduction activities when applicable

GEN.81000 Written QM Program **Phase II**

The biorepository has a written quality management (QM) program.

NOTE: There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program. If the biorepository is part of a larger organization, the biorepository QM program is coordinated with the organization's QM plan.

REFERENCES

1) ISO Standards compendium: ISO 9001:2000, Quality management systems -- Requirements. Geneva, Switzerland: International Organization for Standardization, 2000
2) ISO 15189:2003 Medical laboratories -- Particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2003

GEN.81100 QM Implementation **Phase II**

The QM plan is implemented as designed and is reviewed annually by the director for effectiveness.

NOTE: 1) This requirement pertains to biorepositories that have been CAP accredited for more than 12 months. 2) Appraisal of program effectiveness may be evidenced by an annual written report, revisions to policies and procedures, or revisions to the QM plan, as appropriate.

Evidence of Compliance:

✓ Evidence that the plan has been implemented as designed requires all of the following:
- quality measurements and assessments specified in the plan are being substantially carried out;
- there is evidence of active review of quality measurements;
- any interventions or changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay recorded; **AND**
- any communication of information that is required by the plan have taken place

GEN.81200 QM Error and Incident Management **Phase II**

The QM system includes a program to identify and evaluate errors, incidents, and other problems that may interfere with functions of the biorepository.

NOTE: There must be an organized program for recording of problems involving the biorepository that are identified internally, as well as those identified through outside sources such as complaints from other study collaborators or researchers. Any problem that could potentially interfere with research result integrity or safety must be addressed. Scientific impact, rather than business or management issues, should be emphasized.

The biorepository must:

1. *Record investigation and resolution of these problems*
2. *Perform root cause analysis of any unexpected sentinel events*
3. *Be able to demonstrate any appropriate risk-reduction activities based on such root cause analyses*

REFERENCES
1) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003 (4.8)
2) ISO International Standard 14971: Medical devices—Application of risk management to medical devices. Second edition, 2007-03-01

GEN.81300 QM Indicators of Quality **Phase II**

The QM program includes monitoring key indicators of quality.

NOTE: Key indicators are those that reflect activities critical to expected outcome or that have been problematic in the past. The biorepository must record comparison of performance of selected indicators against a benchmark, where available and applicable. New programs or services should be measured to evaluate their impact on service. The number of monitored indicators should be consistent with the biorepository's scope of service. Action plans should be developed for any indicator in which the biorepository falls outside a predetermined level.

*****NEW** 08/17/2016***

GEN.81325 Correction of Biorepository Records **Phase II**

The biorepository follows a written policy for the management and correction of biorepository records, including quality control data, temperature logs, and intermediate test results or worksheets.

NOTE: Biorepository records and changes to such records must be legible and indelible. Original (erroneous) entries must be visible (i.e. erasures, white and correction fluid are unacceptable) or accessible (e.g. 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.

Evidence of Compliance:
- ✓ Records of corrections to biorepository records following the policy

GEN.81350 Hand-Off Communication **Phase I**

The biorepository implements a procedure for effective "hand-off" communication.

NOTE: The biorepository must have a procedure for communicating information about pending processes, quality or operational 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 or departments

GEN.81400 Employee Quality Communication **Phase II**

The biorepository has a procedure for employees, participants, and researchers to communicate concerns about research misconduct, quality, and safety to management.

NOTE: The biorepository must have a procedure that encourages employees to communicate any concerns or complaints with respect to the research misconduct, quality and safety. The investigation and analysis of employee complaints and suggestions, with corrective or preventive action as appropriate, should be a part of the quality management program and be specifically addressed in quality management records.

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

*****REVISED** 08/21/2017***
GEN.81500 CAP Sign **Phase II**

The biorepository prominently posts the official CAP sign regarding the reporting of quality concerns to the CAP.

NOTE: Biorepositories that have applied to the CAP for accreditation that are not yet accredited must post the sign provided with the CAP application materials. Once a biorepository is accredited, the biorepository receives the official sign for posting.

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

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.

GEN.81600 Customer Satisfaction **Phase I**

Customer satisfaction with biorepository services was measured within the past 2 years.

Evidence of Compliance:
- ✓ Records of physician/client satisfaction survey **OR** referral statistics **OR** complaint rates

GEN.81700 Notifications From Vendors **Phase II**

The biorepository manages notifications from vendors of defects or issues with supplies or software that may affect biobanking related efforts.

NOTE: Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The biorepository should take action on those that have the potential to affect biorepository services.

Evidence of Compliance:

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

GEN.81800 State/Local Regulations **Phase II**

The biorepository has a policy for ensuring compliance with applicable international, federal, state, and local laws and regulations.

NOTE: Applicable international, federal, state, and local requirements may include but are not limited to the following areas: handling radioactive materials, shipping infectious or diagnostic materials, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, participant consent, confidentiality of results, storing and handling Select Agents, proper storage of flammable materials, donation of blood, complying with all safety issues for storage of bulk fuels, e.g. diesel and liquid nitrogen, and whether a Material Transfer Agreement is needed. The checklists contain specific requirements on these areas.

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

*****REVISED** 08/21/2017***

GEN.81900 Terms of Accreditation **Phase II**

The biorepository has a policy that addresses compliance with the CAP terms of accreditation.

NOTE: The CAP terms of accreditation are listed in the biorepository's official notification of accreditation. The policy must include notification of CAP regarding the following:

1. *Investigation of the biorepository by a government entity or other oversight agency, or adverse media attention related to biorepository performance; notification must occur no later than two working days after the biorepository learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. FDA, OSHA, FAA).*
2. *Change in biorepository test menu (notification must occur prior to implementing scope of service changes)*
3. *Change in location, ownership or directorship of the biorepository; notification must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than two working days afterwards*
4. *Discovery of actions by biorepository personnel that violate national, state or local regulations*

In addition, the policy must address:

5. *Provision of a trained and appropriately experienced inspection team comparable in the size and scope of biorepository services if requested by the CAP at least once during the three-year accreditation period.*
6. *Adherence to the Terms of Use for the CAP Certification Mark of accreditation*

Evidence of Compliance:

✓ Records of notification, if applicable

*****NEW** 08/21/2017***

GEN.81910 Interim Self-Inspection **Phase II**

The biorepository has conducted a thorough interim self-inspection and has corrected all deficiencies.

NOTE: The interim self-inspection is an important aspect of continuing education, biorepository improvement, and continuous compliance. Biorepositories must retain records of the CAP self-inspection, as well as the corrective action for deficiencies, as part of the quality management program. The biorepository 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

REFERENCES
1) Clinical and Laboratory Standards Institute. *Assessments: Laboratory Internal Audit Program; Approved Guideline.* CLSI document QMS15-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2013.

GEN.81950 Selection and Evaluation of Services **Phase II**

There is a written procedure for evaluating and selecting biospecimen source sites, contracted services, or referral laboratories, to ensure that specimens and test results are managed in a quality environment.

NOTE:

1. *A written qualification process suitable for the process being performed is in place, e.g. vendor qualification, a system for the biorepository director to approve the service provider.*
2. *Specimens used for patient treatment decisions, including those from clinical trials, should be obtained or sent to a laboratory accredited by CAP, accredited to an established international standard from a recognized organization, or certified by an appropriate government agency.*
3. *It is the responsibility of the biorepository director or designee to monitor the quality of test results received from contracted services or referral laboratories.*

Evidence of Compliance:

✓ Records of evaluation or qualification (e.g. certification, publications, audits or biorepository director-approved records of acceptable quality)

PERSONNEL

The biorepository should have an organizational chart, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files should contain records of educational qualifications, references, training, competency assessments, health records and continuing education records for each employee. Ideally, these files should be located in the biorepository. However, they may be kept in the personnel office or health clinic if the biorepository has ready access to them (i.e. they are easily available to the inspector).

Inspector Instructions:

	• Sampling of personnel policies and procedures • Organizational chart or narrative description • Sampling of all personnel files and competency assessments • Written delegation of duties and functions
	• Do you have a specific example of an employee who demonstrated unacceptable competency assessments? What were the corrective actions? • What continuing education classes are available to employees? • How does the Director meet the director oversight responsibilities?

DIRECTOR QUALIFICATIONS

***REVISED** 08/21/2017*

GEN.82000 Director Qualifications **Phase II**

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

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

***REVISED** 08/17/2016*

GEN.82100 Delegation of Functions **Phase I**

Delegation of the biorepository director's functions or responsibilities is in writing.

NOTE: Functions that may be delegated include duties, such as review of QC processes, ensuring that IRB protocols are followed, and implementation of the quality management plan. The biorepository director remains responsible that all persons performing delegated functions are qualified to do so and that delegated functions are properly carried out.

Functions that may not be delegated include provision of appropriately trained supervisory and technical staff and the identification of their responsibilities. The biorepository director must document personal, on-site assessment of physical and environmental conditions and the adequacy of staffing.

The responsibilities and duties of supervisors, consultants, and personnel involved in the biorepository services must be defined in writing, with records of authorization to perform the services and the level of supervision required, as applicable.

If there are multiple occasions when delegated duties are not being properly performed by the designee and there is a lock of consistency in performing corrective action, the team leader should cite this requirement as a deficiency, in addition to the specific checklist requirement(s) that relates to the duty not being performed (e.g. QC review). This may be overarching rather than a single issue.

Evidence of Compliance:

- ✓ Policy or statement signed by the biorepository director authorizing individuals by name or job title to perform tasks on behalf of the biorepository director **AND**
- ✓ Records showing that delegated tasks are performed by the designee, as required

DIRECTOR OVERSIGHT RESPONSIBILITIES

GEN.82200 Director Responsibility/Authority **Phase II**

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

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

GEN.82300 Effective QM **Phase II**

The biorepository director ensures an effective quality management program for the biorepository.

NOTE: The biorepository director must be involved in the design, implementation, and oversight of the biorepository's quality management program. The program must include monitoring of key indicators, investigation of problems, with corrective and preventive actions as appropriate; maintenance of safety; and ensuring the quality data.

Evidence of Compliance:
Written QM plan covering all areas of the biorepository and addressing all phases of testing

REFERENCES

1) Clinical and Laboratory Standards Institute. *Nonconforming Event Management,* 2nd ed. CLSI guideline QMS11-ED2. Clinical and Laboratory Standards Institute, Wayne, PA; 2015.

GEN.82400 Policy and Procedure Development **Phase II**

The biorepository director is involved in development of all policies and procedures.

GEN.82500 Director's Responsibilities **Phase II**

The biorepository director must have policies to safeguard that:

1. **IRB protocols and policies are upheld**
2. **HIPAA is not violated**
3. **Clinical care is not compromised in the process of procuring biospecimens**
4. **Basic ethical standards related to biospecimen collection and distribution are upheld (e.g. no selling tissues for a profit on the side)**

GEN.82600 Director Responsibility - Education/R&D **Phase II**

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

GEN.82700 Director Responsibility - Personnel **Phase II**

The biorepository director ensures that there are sufficient personnel with adequate training and experience to meet the needs of the biorepository, and that such training and experience is recorded.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI Document QMS03-A3. (ISBN 1-56238-531-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, PA 19087-1898 USA, 2009.

GEN.82800 Director Responsibility - Safe Environment **Phase II**

The biorepository director ensures implementation of a safe environment in compliance with good practice and applicable regulations.

NOTE: The biorepository director must ensure compliance with OSHA and state/local regulations, as well as other applicable safety regulations.

DIRECTOR NOT ON-SITE FULL TIME

NOTE TO THE TEAM LEADER: The following requirements apply to biorepository directors who are not present full-time at the biorepository.

***REVISED** 08/17/2016*
GEN.82900 Director Off-Site **Phase II**

There is a written agreement defining the frequency of, and responsibilities for, activities to be performed by the biorepository director during on-site visits and remotely, with records of the director's completed activities.

Evidence of Compliance:
- ✓ Records that show the frequency of on-site visits **AND**
- ✓ Meeting minutes showing director participation

***REVISED** 08/17/2016*
GEN.83000 Director Visit **Phase II**

The involvement of the biorepository director in the biorepository's activities conducted during on-site visits or remote consultation follows the written policy or agreement and is considered adequate by the biorepository staff and the inspection team.

NOTE: The requirement is not met if the biorepository management and staff identify inadequate oversight by the biorepository director. If activities are conducted remotely, the biorepository director must ensure that there is an effective communication mechanism in place between the biorepository director and biorepository management and staff.

Evidence of Compliance:
- ✓ Minutes from meetings with staff **OR**
- ✓ Records of conformance with specified director responsibilities

OPERATIONAL LEADERSHIP/MANAGEMENT SECTION

GEN.83100 Leadership/Management Qualifications **Phase II**

Leadership/management have qualifications equal to the expertise of the level of service of the biorepository.

GEN.83200 Organizational Chart **Phase I**

There is an organizational chart for operational leadership, or a narrative description that describes the reporting relationships among the owner or management, the biorepository director, and management/leadership staff, as appropriate.

GEN.83300 Description of Duties **Phase I**

Duties for all staff are described in writing so that it is clear who is responsible for consent, banking, transport, inventory, triage, and release on any given day.

GEN.83400 Staff Qualifications **Phase II**

The biorepository director must define the minimum qualifications for each role in the biorepository based on the level of service of the biorepository.

Evidence of Compliance:
- ✓ Written description of minimum qualifications

GEN.83500 Continuing Education **Phase I**

There is a functional, continuing biorepository education program adequate to meet the needs of the biorepository's mission and/or goals as outlined by the biorepository director.

NOTE: Continuing education may take place within the institution or at an offsite presentation.

Evidence of Compliance:
- ✓ Written policy for continuing education

REFERENCES
1) VonNeeda P. Keep everyone keen on continuing education. *Med Lab Observ*. 1979(May):117-126

*****NEW** 08/21/2017***

GEN.83510 Biorepository Personnel Evaluation Roster **Phase II**

The Biorepository Personnel Evaluation Roster is current and accurate and is audited by the biorepository director or designee at least annually.

Evidence of Compliance:
- ✓ Records of completed rosters accurately reflecting personnel **AND**
- ✓ Records of annual audits performed by the biorepository director or designee

*****REVISED** 08/21/2017***

GEN.83600 Personnel Records **Phase II**

Personnel records are maintained (in electronic or paper format) and readily available for all current technical personnel and include all of the following, as applicable.

1. **Copy of academic diploma , transcript, or primary source verification (PSV) reports confirming credentials, if applicable (Refer to the NOTE for use of PSV reports)**
2. **Personnel license, if required by state**
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 biorepository 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 director review is required to report participant 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: All records in either electronic or paper form must be readily available for review by the inspector at the time of the CAP inspection.

If PSV reports are used, the biorepository 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. If there are required elements for the qualification that the PSV report does not adequately verify (e.g. transcripts, educational equivalency for personnel trained outside of the US, or reports lacking the type of degree earned), there must be records showing that qualifications are met using other means.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI Document QMS03-A3. (ISBN 1-56238-531-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, PA 19087-1898 USA, 2009.

GEN.83700 Personnel Training — Phase II

There are records of satisfactory completion of training of all personnel on all instruments/methods applicable to their designated job.

NOTE: The records must show that training specifically applies to the duties performed by each individual.

Retraining must occur when problems are identified with an individual's performance.

GEN.83800 Competency Assessment — Phase II

The competency of personnel to perform their assigned duties is assessed.

NOTE: Prior to the initiation of job duties and the performance of new duties, each individual must have training and be evaluated for proper performance of duties as required in GEN.83700.

After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of competency must occur when problems are identified with an individual's performance. Elements of competency assessment include but are not limited to:

1. *Direct observations of routine process and procedure performance, including as applicable, participant identification and preparation; and specimen collection, handling, processing*
2. *Review of results or worksheets, quality control records, and preventive maintenance records*
3. *Direct observation of performance of instrument maintenance and function checks, as applicable, and*

4. Evaluation of problem-solving skills

Many of the elements of competency assessment are performed during routine supervisory review of personnel throughout the year. Records of these elements, including adherence to biorepository policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed during routine supervisory review, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment by routine supervisory review may be recorded using a checklist.

Evidence of Compliance:

- ✓ Records of competency assessment for new and existing personnel reflecting the specific skills assessed, the method of evaluation

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Training and Competence Assessment; Approved Guideline—Third Edition*. CLSI Document QMS03-A3. (ISBN 1-56238-531-3). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 2500, Wayne, PA 19087-1898 USA, 2009.

GEN.83900 Competency Corrective Action **Phase II**

If an employee fails to demonstrate satisfactory performance on the competency assessment, the biorepository 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 biorepository'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 biorepository director.

Evidence of Compliance:

- ✓ Records of corrective action to include evidence of retraining and reassessment of competency
- ✓ Written procedure for competency assessment corrective action

PHYSICAL FACILITIES

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 and safety, in which case they become a Phase II deficiency. As biorepository operations expand over time, Phase I space deficiencies may become Phase II deficiencies by the time of the next inspection.

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.

Inspector Instructions:

	• Floor plan and equipment locations • Overview of Building Automation System (BAS), if available • Sampling of electrical grounding records, if applicable
	• Physical facility (adequate space, acceptable temperature/humidity, areas clean, adequate storage areas, adequate emergency power, oxygen sensors, or sufficient airflow) • Perimeter security and access security to specific specimen collections
	• Is the work area sufficient for you to perform your duties safely and accurately?

GEN.84000 Restricted Access **Phase I**

Access to the biorepository is restricted to authorized individuals.

NOTE: This may be accomplished through the use of access codes (security codes, user codes) that limit individuals' access to those areas they are authorized to enter or use. Authorization is required for access to the:

1. *Biorepository*
2. *Specimens, aliquots and any extracts thereof*
3. *Participant/client and study records*

Access codes/user codes must be maintained and current (e.g. inactivated when employment of an authorized individual's employment ends).

GEN.84100 Adequate Space **Phase II**

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

REFERENCES

1) Mortland KK, Reddick JH. Laboratory design for today's technologies and marketplace. *Lab Med.* 1997;28:332-336
2) Clinical and Laboratory Standards Institute. *Laboratory Design;* 3rd ed. CLSI guideline QMS04-ED3. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.

GEN.84200 Adequate Space **Phase I**

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

1. **Biorepository director**
2. **Staff pathologists and researchers**
3. **Biorepository technicians**
4. **Clerical staff**
5. **Chief technologist/biorepository manager**
6. **Section supervisors**
7. **Freezer storage area**
8. **Ambient temperature storage**
9. **Lavatories**
10. **Library, conference and meeting room**

11. Personnel lounge and lockers

GEN.84300 Climate Control **Phase I**

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

Evidence of Compliance:
- ✓ Temperature and humidity records, if specific ranges are required for instrument and/or reagent use

GEN.84400 HVAC **Phase I**

HVAC units, if present, are properly serviced and functioning to maintain appropriate compressor activity.

Evidence of Compliance:
- ✓ Records of maintenance

GEN.84500 Hallway Obstructions **Phase II**

Passageways are unobstructed.

GEN.84600 Environment Maintenance **Phase I**

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

GEN.84700 Environment Maintenance **Phase I**

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

GEN.84800 Environment Maintenance **Phase II**

There are oxygen sensors or sufficient airflow to prevent asphyxiation in areas where liquid nitrogen is used.

GEN.85100 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.

Evidence of Compliance:
- ✓ A written procedure detailing relevant personnel, when to order supplies and levels of buffer stock required

REFERENCES
1) Chapman J. Saving money with computerized materials management. *Advance/Lab.* 1999:8(9):16-18

GEN.85200 Intrabiorepository Storage **Phase I**

The intrabiorepository storage area is sufficient and free of clutter.

GEN.85300 Emergency Power **Phase II**

Emergency power is adequate for the functioning of the biorepository.

NOTE: Emergency power supply must be adequate for refrigerators, freezers, incubators, etc., to ensure preservation of specimens.

GEN.85400 Emergency Power Load Testing **Phase II**

Load testing is performed to ensure that emergency power is adequate for the functioning of the biorepository.

NOTE: Emergency power supply must be adequate for refrigerators, freezers, incubators, etc. to ensure preservation of specimens.

GEN.85420 Electrical Grounding **Phase II**

There are records that all instruments and appliances are checked for adequate grounding and 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 (GFCI) protection built-in need not be checked for current leakage*
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.

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 are available, they must be followed.

REFERENCES
1) Occupational Safety and Health Administration. Electrical. Use of equipment. US Government Printing Office, 1999(Jul 1): [29CFR1910.334]

GEN.85500 Contingency Plans **Phase II**

Contingency plans are in place in the event that the back-up generator is not operational and if there is not enough fuel present to operate the generator.

Evidence of Compliance:
- ✓ Written contingency plan **AND**
- ✓ Schedule of fuel deliveries

SAFETY

Requirements in this section cover the general safety program for the entire biorepository.

GENERAL SAFETY

Inspector Instructions:

	• Sampling of safety policies and procedure • Ergonomic evaluation • Sampling of personnel safety training records
	• Adequate emergency lighting • Flammable and combustible liquids and gas cylinders (properly stored) • Emergency eyewash available and tested properly
	• How are your biorepository's safe work practices reviewed? • Is there a specific example of an occupational injury or illness that required medical treatment? What steps were taken to address the incident?
	• For any occupational injury or illness that required medical treatment, further evaluate leadership's responses, corrective actions, follow-up procedures, and additional measures taken to ensure safety in the workplace

GEN.85600 Safety Policy and Procedure Approval **Phase II**

The biorepository director or designee reviews and approves all changes to the safety policies and procedures before implementation.

GEN.85700 Safety Policy and Procedure Availability **Phase II**

There are records for the training of all personnel in safety.

NOTE: A system to ensure that all personnel have read the policies and procedures is required and must form a portion of the orientation program for new personnel. Posting of specific warnings or hazards as appropriate is urged.

Evidence of Compliance:

✓ Records of personnel review of safety policies and procedures

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

GEN.85800 Safe Work Practices Review **Phase II**

There are records of periodic review (at least annually) of safe work practices to reduce hazards.

NOTE: Review must include bloodborne hazard control and chemical hygiene. If the review identifies a problem, the biorepository must investigate the cause and consider if modifications

are needed to safety policies and procedures to prevent reoccurrence of the problem or mitigate the potential risk.

Evidence of Compliance:

✓ Safety committee minutes **OR** records of regular safety inspections **OR** incident reports and statistics **OR** another method defined by the biorepository director

GEN.85820 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. Biorepository activity, workplace and equipment (e.g. chairs, 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

REFERENCES

1) U.S. Dept. of Labor, Occupational Safety and Health Administration. Ergonomic safety and health program management guideline. 54 *Fed Register* 3904 (1989), modified at 29CFR1910)

GEN.85900 Accidents **Phase II**

There are written policies and procedures for the reporting and recording of all accidents resulting in property damage or involving spillage of hazardous substances.

GEN.85920 Gas Cylinder Storage **Phase II**

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

GEN.85940 Flammable Gas Cylinders **Phase II**

Flammable gas cylinders 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*

REFERENCES

1) National Fire Protection Association Standard 55: Compressed Gases and Cryogenic Fluids Code, 2013 edition

GEN.85960 Liquid Nitrogen and Dry Ice **Phase II**

Adequate policies, procedures, and practices are in place for the use of liquid nitrogen 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 when decanting or entering an open container of LN2*

2. *The mandatory use of insulated loose-fitting 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*
4. *Availability of a Safety Data Sheet*

REFERENCES
1) OSHA Quick Facts: Laboratory Safety Cryogens and Dry Ice. Occupational Safety and Health Administration Website. https://www.osha.gov/Publications/laboratory/OSHAquickfacts-lab-safety-cryogens-dryice.pdf. Reviewed October 2011. Accessed 11/24/2015.

GEN.86000 Occupational Injuries **Phase II**

There are written policies and procedures for the reporting of all occupational injuries or illnesses that require medical treatment (except first aid).

NOTE: For US facilities 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 or losses of an eye within 24 hours.

REFERENCES
1) Occupational Safety and Health Administration. Improve Tracking of Workplace Injuries and Illnesses; Final Rule, *Fed Register*. Vol. 81, No. 93, 29CRF Part 1904 and 1902. May 12, 2016.

GEN.86100 Occupational Injury Evaluation **Phase II**

An evaluation of these reports of biorepository accidents and occupational injury/ illnesses is incorporated into the biorepository's quality management program to avoid recurrence.

Evidence of Compliance:

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

GEN.86120 Excessive Noise **Phase II**

The biorepository has a policy to protect personnel from excessive noise levels.

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

REFERENCES
1) U. S. Department of Labor, Occupational Safety & Health Administration: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9735&p_table=STANDARDS

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GEN.86130 Emergency Eyewash **Phase II**

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

NOTE The chemical hygiene plan must include provisions for the safe handling of all chemicals used in the biorepository. 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.

Immediate and prolonged (15 minutes) flushing is generally necessary for corrosive/alkali agents. If the water is not at an appropriate temperature, it may add to the injury.

The eyewash facilities must meet the following criteria:

1. *No greater than 10 seconds travel distance from areas in the biorepository where hazardous chemicals are present*
2. *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 15°C and 37°C (60-100°F). Actual temperature recording is not required)*
5. *Plumbed systems are activated weekly*
6. *Self-contained units are visually examined weekly*

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

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*

For self-contained eyewash facilities, the manufacturer's specifications should be available for review by an inspector. The availability of disposable eyewash bottles in the work area does not replace the need for an eyewash facility in the areas at risk for eye exposure from corrosive chemicals.

REFERENCES
1) American National Standards Institute. Emergency eyewash and shower equipment. New York, NY: ANSI, 2004;Z358.1
2) Occupational Safety and Health Administration. Medical and first aid. Medical services and first aid. US Government Printing Office, 1998(June 18):[29CFR1910.151(c)]

GEN.86140 UV Light Exposure **Phase II**

There are 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, 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

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GEN.86200 Emergency Preparedness **Phase II**

There are written policies and procedures defining the role and responsibilities of the biorepository in emergency preparedness for harmful or destructive events or disasters.

NOTE: The specific elements to be included in the emergency preparedness 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. Written policies and procedures must be developed to support the execution of the biorepository's emergency response plan and the path of workflow, including a communication plan. Biorepositories 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 biorepository 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 (e.g. HVAC, water, communication, computer system), power failures, natural disasters (e.g. tornado, hurricane, earthquake, fire, flood), emerging public health threats, cyber-attacks, terrorist events, or workplace violence.

REFERENCES
1) Clinical and Laboratory Standards Institute. *Planning for Laboratory Operations During a Disaster; Approved Guideline.* CLSI document GP36-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2014.

GEN.86300 Evacuation Plan **Phase II**

There is a written comprehensive and workable evacuation plan specific for the facility.

NOTE: 1) This plan must cover all personnel and visitors, and must address the special needs of persons with disabilities. Evacuation routes must be clearly marked (Posting evacuation routes is optional). 2) Emergency lighting is adequate for safe evacuation of the biorepository.

REFERENCES
1) Occupational Safety and Health Administration. Exit routes, emergency action plans, and fire prevention plans: standard, 2002 [29CFR1910.38]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

BIOLOGICAL SAFETY

Inspector Instructions:

	• Sampling of biological safety and waste disposal policies and procedures • Sampling of sterilizing device monitoring records • Sampling of records of hepatitis B vaccination or records declining the vaccination • Sampling of specimen transport procedures
	• PPE usage • Biohazard disposal bins
	• What has your facility done to reduce or eliminate exposure to bloodborne pathogens? • How does your biobank dispose of sharps?

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GEN.86400 Bloodborne Pathogens **Phase II**

The biorepository has written policies and procedures for infection control that comply with the OSHA Standard on occupational exposure to bloodborne pathogens and to the institution's exposure control plan.

NOTE: Universal or standard precautions must be used when handling all blood and body fluid specimens. 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 participant or participant 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. Policies must comply with the OSHA Standard on Bloodborne Pathogens. The facility's exposure control plan must address potential hazards that biorepository visitors may encounter.

Evidence of Compliance:

- ✓ Safety manual **AND**
- ✓ Records of universal precaution training for all personnel expected to have contact with body fluids

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
2) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014

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GEN.86500 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 in which blood and body substances are handled and in circumstances during which exposure is likely to occur.

NOTE: 1) Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious materials to pass through to the skin or reach work clothes, skin, footwear, etc. In addition to fluid-resistant gowns, aprons may be required if exposure to large volumes of body fluids is anticipated. 2) OSHA requires unpowdered gloves to be worn with each participant or subject contact and changed after contact when performing vascular access procedures. Hands must be cleaned after glove removal using an effective antimicrobial method. 3) PPE is made available to biorepository visitors, as applicable.

REFERENCES

1) Centers for Disease Control. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR.* 1989:38(suppl S-6):1-37
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
3) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014
4) Food and Drug Administration. Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove; final rule, *Fed Register.* 2017 (Jan 18): 81 FR 91722.

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GEN.86600 PPE Instruction **Phase II**

Personnel are instructed in the proper use of personal protective clothing/equipment (*e.g.* gloves, gowns, masks, eye protectors, footwear).

NOTE: The required elements of training in the use of gloves include (a) Proper fitting of gloves; (b) Replacing gloves immediately when torn or contaminated; (c) Not washing or disinfecting gloves for reuse; (d) Using hypoallergenic gloves when indicated by patient or health care provider history; (e) Decontamination of hands after glove removal using an effective antimicrobial method.

Evidence of Compliance:

- ✓ Written policy for the use of PPE for specific tasks **AND**
- ✓ Records of PPE training

REFERENCES

1) Department of Labor, Occupational Safety and Health Administration, Occupational Safety and Health Standards. Bloodborne pathogens. *Fed Register.* 2002(July 1): [29CFR1910.1030(d)(3)(i)]

2) Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51.
3) World Health Organization. WHO Guidelines on Hand Hygiene in Health Care, 2009. http://apps.who.int/iris/bitstream/10665/44102/01/9789241597906_eng.pdf, accessed 12/5/2015.

GEN.86620 Latex Allergy — Phase II

The biorepository has a written program to protect personnel and participants/clients 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

GEN.86630 Manual Manipulation of Needles — Phase II

There is a written policy that 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.

REFERENCES

1) Jagger J, *et al*. Rates of needlestick injury caused by various devices. *New Engl J Med.* 1988;319:284-288
2) Whitby M, *et al*. Needlestick injury: impact of a recapping device and an associated education program. *Infect Control Hosp Epidemiol.* 1991;12:220-225
3) Bush VJ, *et al*. Advancements in blood collection devices. *Lab Med.* 1998;29:616-622
4) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615
5) Charney E. Retractable safety syringe activation study. *J Healthcare Safety Compliance Infect Control.* 1998;2(9):413-415
6) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
7) Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline.* 4th ed. CLSI Document M29-A4. Clinical and Laboratory Standards Institute, Wayne, PA; 2014

GEN.86640 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: Under US law, 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.

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
2) Occupational Safety and Health Administration. Enforcement procedures for the occupational exposure to bloodborne pathogens. Washington, DC: U.S. Government Printing Office, OSHA Directive CPL 2-2.44D, 1999 (Nov 5)

3) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

GEN.86650 Eating/Mouth Pipetting — Phase II

There is a written policy that prohibits smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas.

NOTE: The biorepository must define the technical work area in particular when there is space sharing.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.86700 Specimen Transport Procedures — Phase II

There are written procedures for the procurement, transportation, and handling of biospecimens (e.g. blood, body fluids, tissue) to ensure that all specimens are submitted in an appropriately labeled and well-constructed container with a secure lid 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 biorepository must have procedures to respond to a spill within the tube, including appropriate decontamination measures.

REFERENCES

1) Centers for Disease Control and Prevention. Evaluation of safety devices for preventing percutaneous injuries during phlebotomy procedures. *MMWR.* 1997;46(2):1
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.86800 Spill Handling — Phase II

There are written procedures for handling spills of blood and other body fluids.

GEN.86900 Hepatitis B Vaccinations — Phase II

Personnel reasonably expected to have direct contact with body fluids are identified and offered hepatitis B vaccinations free of charge.

Evidence of Compliance:

✓ Written policy offering the hepatitis B vaccination to personnel

REFERENCES

1) Centers for Disease Control. Protection against viral hepatitis: recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR.* 1990;39:#RR-2
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]

GEN.87000 Viral Exposure — Phase II

There is a policy for post-exposure 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 subject after consent is obtained**
2. **Appropriate clinical and serologic evaluation of the 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

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]4)

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GEN.87020 Biohazard Disposal **Phase II**

All infectious wastes (*e.g.* glassware, blood collection tubes, microbiologic and tissue specimens) and other contaminated materials are discarded into "biohazard"-labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the work area for storage and disposal.

NOTE: Waste disposal must be in accord with all regulations and disposed of with minimum danger to professional, technical, and custodial personnel.

All infectious wastes must be incinerated or appropriately decontaminated before being sent to a sanitary landfill.

Evidence of Compliance:

✓ Written procedure for waste disposal in accordance with local regulations

REFERENCES

1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

GEN.87100 TB Exposure Plan **Phase II**

The biorepository has a written tuberculosis exposure control plan.

NOTE: This plan must include an exposure determination at defined intervals for all personnel who may have occupational exposure to tuberculosis. Additional elements of the plan include engineering and work practice controls for hazardous activities that potentially may aerosolize Mycobacterium tuberculosis. Such activities include the handling of unfixed tissues in surgical pathology or autopsies.

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 NIOSH-approved filter respirator (N-95 or higher) or a powered air-purifying respirator (PAPRS) equipped with high efficiency particulate air (HEPA) filters. Accurate fit testing is a key component of effective respirator use.

REFERENCES

1) Centers for Disease Control and Prevention/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Washington, DC: US government printing office, Feb 2007
2) CDC. Guidelines for preventing transmission of Mycobacterium tuberculosis in health care settings. *Morb Mortal Weekly Reports.* 2005;54(RR17):1-141.

GEN.87125 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 activity. Weekly monitoring is recommended.

Evidence of Compliance:

- ✓ Written procedure for monitoring sterilizing devices **AND**
- ✓ Records of monitoring at defined frequency

FIRE SAFETY

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

Inspector Instructions:

READ	• Sampling of fire safety policies and procedures • Sampling of fire safety training records
OBSERVE	• Automatic fire extinguisher systems, if required • Two exit access doors, if required • Audible automatic fire detection and alarm system • Fire alarm station • Portable fire extinguishers, where appropriate

GEN.87200 Fire Prevention Policies and Procedures **Phase II**

Policies and procedures are written and 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.

REFERENCES

1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

GEN.87420 Fire Separation **Phase II**

If the biorepository stores flammable materials, it 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.

Where the biorepository is separated by two-hour construction (rated at 1.5 hours) and Class B self-closing doors (SCD), no AFE system is required. This applies to biorepositories that reside within a hospital or patient-care facility. An AFE system is required for those biorepositories separated from inpatient areas by one-hour construction and Class C SCD if flammable and combustible liquids are stored in bulk. An AFE system is always required if there are unattended biorepository operations employing flammable or combustible reagents. "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 (9.2m²), 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

REFERENCES
1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

GEN.87430 Fire Exit **Phase II**

Each room larger than 1000 ft² (92.9m²), 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.

REFERENCES
1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

GEN.87440 Fire Safety Training **Phase II**

Fire safety training is performed for new employees, with 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 (i.e., 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 (*e.g.* personnel roster with dates of participation, sign-in sheet, etc.)

GEN.87442 Fire Detection/Alarm **Phase II**

There is an automatic fire detection and alarm system.

NOTE: 1) 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. 2) The fire alarm is audible in all parts of the biorepository, including storage areas and lavatories. 3) Facilities employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.

GEN.87444 Fire Alarm Station **Phase II**

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

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

REFERENCES
1) National Fire Protection Association Standard 72: National Alarm and Signaling Code, 2013 edition, Chapter 27.6

GEN.87450 Fire Extinguishers **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.

REFERENCES

1) National Fire Protection Association Standard 10: Standard for Portable Fire Extinguishers, 2013 edition

CHEMICAL SAFETY

Inspector Instructions:

READ	• Sampling of chemical safety policies and procedures • Sampling of SDS (formerly MSDS) sheets • Sampling of formaldehyde vapor monitoring records • Sampling of chemical waste disposal policies and procedures
OBSERVE	• Acids and bases (properly stored) • Sampling of hazardous chemicals (labeling) • PPE usage • Emergency chemical hazard instructions and supplies (spill kit)
ASK	• How does your biobank dispose of hazardous chemicals? • How does your biobank ensure the safe handling of radioactive specimens?

GEN.87600 Chemical Hygiene Plan **Phase II**

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

NOTE 1: The biorepository director or designee must ensure that the biorepository has a written chemical hygiene plan (CHP) that defines the safety policies and procedures for all chemicals used in the biorepository. 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 biorepository.

The purpose of the OSHA regulations 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 biorepository 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*
9. *Evaluation of the carcinogenic potential, reproductive toxicity and acute toxicity for all chemicals used in the biorepository. The product label, safety data sheets (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 biorepository*

NOTE 2: 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 biorepository for carcinogenic potential, reproductive toxicity, and acute toxicity **AND**
- ✓ Written procedure for chemical fume hood function verification **AND**
- ✓ Records of testing

REFERENCES
1) Occupational Safety and Health Administration. Toxic and hazardous substances hazard communication: standard. 2012: [29CFR1910.1200]
2) Occupational Safety and Health Administration. Occupational exposures to hazardous chemicals in laboratories: standard. 2012: [29CFR1910.1450]
3) Karcher RE. Is your chemical hygiene plan OSHA-proof? *Med Lab Observ.* 1993(Jul):29-36
4) Occupational Safety and Health Administration. Occupational exposure to methylene chloride: standard. 1997: [29CFR1910;1915;1926]

GEN.87700 Chemical Safety Document Access — Phase II

For US biorepositories, 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 biorepository**
3. ***Code of Federal Regulations.* Title 29, part 1910.1450 and its appendices**

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.87800 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 biorepository 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 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.

REFERENCES
1) Occupational Safety and Health Administration. Toxic and hazardous substances. Hazard communication. Washington, DC: US Government Printing Office, 2007(Jan 1): [29CFR1910.1200]

GEN.87900 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.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

GEN.88000 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 director must periodically assess its usability.

REFERENCES
1) Occupational Safety and Health Administration. Hazardous materials. Hazardous waste operations and emergency response. US Government Printing Office, 1999(Jul 1): [29CFR1910.120]
2) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Safety; Approved Guideline, Third Edition.* CLSI document GP17-A3 [ISBN 1-56238-797-9 (Print); ISBN 1-56238-798-7 (Electronic)]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2012.

GEN.88020 Hazardous Chemical Waste Disposal — Phase II

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

NOTE: 1) The biorepository is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition. 2) The method for the disposal of all solid and liquid wastes is in compliance with local, state and federal regulations. (Whether or not biorepository management is responsible for waste disposal, the biorepository 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 biorepository director, safety officer or facilities manager to ensure that the biorepository is in compliance with regulations.)

Evidence of Compliance:

✓ Records of review of regulations for compliance

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Clinical Laboratory Waste Management; Approved Guideline—Third Edition*. CLSI document GP05-A3 (ISBN 1-56238-744-8). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2011.

***NEW** 08/17/2016*

GEN.88040 Formaldehyde and Xylene Safety **Phase II**

Formaldehyde and xylene vapor concentrations are maintained below the following maxima, expressed as parts per million, in all areas of the biorepository where formaldehyde or xylene are used.

NOTE: Formaldehyde and xylene vapor concentrations must be monitored in all areas where these reagents are used: e.g. surgical pathology gross dissection room, histology laboratory, etc. Initial monitoring involves identifying all employees who may be exposed at or above the action level or at or above the STEL and accurately determining the exposure of each employee identified. Further formaldehyde monitoring is mandated at least every six months if results of the initial monitoring equal or exceed 0.5 ppm (8 hr time-weighted exposure, the "action level") or at least once per year if the results exceed the short term exposure limit (STEL) 2.0 ppm. The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least seven days apart show that employee exposure is below the action level and the short-term exposure limit, and 1) no change has occurred in production, equipment, process or personnel or control measures that may result in new or additional exposure to formaldehyde, and 2) there have been no reports of conditions that may be associated with formaldehyde exposure.

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 for any employee involved in the activity. If any personnel report signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the laboratory must promptly monitor the affected person's exposure.

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.

	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**

Evidence of Compliance:

- ✓ Written procedure for formalin and xylene safety including action limits, criteria for discontinuation of monitoring and criteria for resumption of monitoring **AND**
- ✓ Record of initial formalin and xylene monitoring and repeat monitoring when indicated **AND**
- ✓ Records of corrective action when exposure limits are exceeded

REFERENCES

1) Montanaro A. Formaldehyde in the workplace and in the home. Exploring its clinical toxicology. *Lab Med.* 1996;27:752-757
2) Goris JA. Minimizing the toxic effects of formaldehyde. *Lab Med.* 1997;29:39-42
3) Wenk PA. Disposal of histology stains. *Lab Med.* 1998;29:337-338
4) Occupational Safety and Health Administration. 29CFR1910.1048 and 1450, revised July 1, 1998

GEN.88100 Flammable Storage **Phase II**

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

NOTE: 1) In each biorepository 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 (9.2m²) 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 (9.2m²).These amounts may be doubled if there is an automatic fire suppression system (e.g. sprinklers). For example: a 1000 ft² (92.9m²) laboratory defined by fire resistant walls/doors can store 10 gallons (37.7 L) outside a safety cabinet and 20 gallons (75.7 L) inside a safety cabinet and double those numbers if there is an automatic fire suppression system. 2) Safety cans should be used for bulk storage of flammable and combustible liquid (National Fire Protection Association classes I and II). 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. Safety cans should be used instead of glass bottles if the purity required does not mandate glass storage.

REFERENCES
1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

GEN.88200 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 health, 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.

REFERENCES
1) National Fire Protection Association Standard 45: Standard on Fire Protection for Laboratories Using Chemicals, 2011 edition

GEN.88300 Acid/Base Storage **Phase II**

Supplies of concentrated acids and bases are stored in cabinets near floor level.

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

GEN.88310 Evacuation/Clean-up Plan **Phase II**

The biorepository has a plan for evacuation and clean-up in the event of an LN2 or liquid CO_2 spill from a bulk source.

GEN.88325 Emergency Treatment - Toxic Fumes **Phase II**

The biorepository has a plan for the immediate treatment of an individual overcome by toxic fumes.

RADIATION SAFETY

GEN.88340 Radiation Safety Manual **Phase II**

If the biorepository handles specimens that are known to be radioactive, there are written policies and procedures adequate for radiation safety.

GEN.88350 Radioactive Material Handling **Phase II**

If the biorepository handles specimens that are known to be radioactive, there are specific policies and procedures for the safe handling of tissues that may contain radioactive material (*e.g.* sentinel lymph nodes, breast biopsies, prostate "seeds", *etc.*).

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

REFERENCES

1) Glass EC, *et al*. Editorial: radiation safety considerations for sentinel node techniques. *Ann Surg Oncol.* 1999:6:10
2) Miner TJ, *et al*. Guideline for the safe use of radioactive materials during localization and resection of sentinel lymph nodes. *Ann Surg Oncol.* 1999;6:75-82
3) Cibull ML. Handling sentinel lymph node biopsy specimens. A work in progress. *Arch Pathol Lab Med*. 1999;123:620-621
4) Pfeifer JD. Sentinel lymph node biopsy. *Am J Clin Pathol.* 1999;112:599-602
5) Barnes CA. False-negative frozen section results. *Am J Clin Pathol.* 2000;113:900
6) Fitzgibbons PL, *et al*. Recommendations for handling radioactive specimens obtained by sentinel lymphadenectomy. *Am J Surg Pathol.* 2000;24:1549-1551