COLLEGE of AMERICAN PATHOLOGISTS

Master

Laboratory General (BAP Only) Checklist

CAP Accreditation Program

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

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Laboratory General Checklist

TABLE OF CONTENTS

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
GEN.74900	08/21/2017
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.

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:

	• 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
	• 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?
	• 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. <u>This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. FDA, OSHA, FAA).</u>*
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

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

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

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

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

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

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

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.

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

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)

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

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:

	• Sampling of fire safety policies and procedures • Sampling of fire safety training records
	• 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:

	• 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
	• Acids and bases (properly stored) • Sampling of hazardous chemicals (labeling) • PPE usage • Emergency chemical hazard instructions and supplies (spill kit)
	• 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