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CAP General Laboratory Checklist Tool

Laboratory (LAB)
Pathology Data System(PDS / Soft) / Laboratory Information System (LIS)
Organizational Policies Johns Hopkins Medical Institutions (JHMI) / Johns Hopkins Medical Laboratories (JHML)
Pathology Department/ CQI Office (CQI)
JHH Safety Manual
Shared function between LIS and Laboratory

			QUALITY MANAGEMENT				
GEN.13806 R	2	**QM Program** The laboratory has a quality management (QM) program.	**NOTE:** The QM program must include processes to ensure quality throughout the pre-analytic, analytic, and post-analytic phases of testing (see GEN.20316). There must be a written that describes the overall QM program. The document must be sufficiently detailed, to describe out the objectives and essential elements of the QM program. If the laboratory is part of a larger institution (eg, a hospital), the laboratory QM program must be integrated with the institution's QM program, as applicable. The QM plan may be based upon some reference resource such as CLSI QMS01-05; the ISO 9000 series or ISO 15189; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL— HPO Path Volume II– Quality management- Management Program	Quality Management program	https://hpo.johnshopkins.edu/hopkins/policies/68/3577/policy_3577.pdf?_=0.055190464894 7
GEN.16902		**Moved GEN 20326**					
GEN.20100 R	2	**QM Extent of Coverage** The QM program cover all areas of the laboratory and all beneficiaries of service. (eg, clinical staff, patients and/or clients).	**NOTE:** The QM program must be implemented in all areas of the laboratory (e.g., chemistry, anatomic pathology, satellite, point-of-care, consultative services, etc.). The program must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and referral laboratory services.		HPO--PATHOLOGY VOLUME II GENERAL POLICY MANUAL-- Quality management- Management System.**QM003**	https://hpo.johnshopkins.edu/hopkins/policies/68/3578/policy_3578.pdf?_=0.039136990508 8	
GEN.20208 R	2	**QM Patient Care/Client Services** The QM program include a process to identify and evaluate non-conforming events.	**NOTE:** Non-conforming events include problems such as errors, and incidents that may interfere with patient care/client services. (see the Definition of Terms). There must be an organized process for recording problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The process must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care/client services or safety must be addressed. Clinical, rather than business/financial issues, should be emphasized. The laboratory must record investigation, resolution, and follow-up of these events.		HPO--PATHOLOGY VOLUME II GENERAL POLICY MANUAL-- Quality management- Management System. *Occurrence management **HERO *Hopkins Event Reporting Online* * Hospital event system	http://www.insidehopkinsmedicine.org/hpo/policies/68/3578/policy_3578.pdf	http://intranet.insidehopkinsmedicine.org/patient_safety_net
GEN.20310 R	2	**Investigation of Non-conforming Events** The QM program requires a root cause analysis (RCA) when a non-conforming event occurs that results in death, permanent harm or severe temporary harm (eg, sentinel event). For non-conforming events that represent a risk to patients, donors, employees, or the health and safety of the general public, but are not sentinel events (eg, near misses), the QM program includes a process to define the scope and extent of the investigation required.	NOTE: An RCA is a systematic process for identifying the causal factor(s) that underlie errors or potential errors in care. By conducting an RCA and addressing root causes, the laboratory may be able to substantially or completely prevent the same or similar incident from recurring. Laboratories must demonstrate appropriate risk-reduction activities based on such RCAs. Helpful tools on RCA can be found on cap.org on the CAP15189 Accreditation Program landing page. RCA poster	*✓Written QM policy and procedure for performing a root cause analysis or investigation of nonconformities AND* *✓Records of root cause analysis and other nonconformity investigations*	CAP15189 Accreditation Program	RCA poster	
GEN.20316 R	2	**QM Indicators of Quality** The QM program include monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases by regularly comparing performance against targets defined by the laboratory.	**NOTE:** Key indicators must monitor activities integral to patient care delivery. The number of monitored indicators, as determined by the laboratory director, must be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories must monitor multiple aspects of the testing process appropriate to their scope of service. While there is no requirement to monitor any specific laboratory indicator, the following key quality indicators have been commonly used to measure laboratory performance in a consistent manner and are important to clinicians and patients as indices of care. ● Patient/Specimen Identification: Percent of patient wristbands with errors, (ie, mislabels), percent of ordered tests with patient identification errors, or percent of results with identification errors. ● Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer. ● Specimen Acceptability: Percent of specimens received that are suitable for testing. ● Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered. This may include orders of a "stat" priority (eg, emergency department or intensive care unit specimens) or routine priority, to include the percent of specimens with turnaround time that falls within an established limit (eg, the time that represents the 90th or 95th percentile of turnaround times or less than 30 minutes). ● Troponin Turnaround Time: Specific clinical stat turnaround time metrics (eg, order to result availability, specimen collection to result availability) ● Critical Result Reporting: Percent of critical results with written record that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time	*✓Listing of quality indicators that address all phases of testing and are appropriate for the scope of testing and laboratory services AND* *✓Defined targets for evaluating quality indicator monitoring data AND* *✓Quality indicator monitoring data and evaluation at laboratory defined frequency, including comparison against targets based on benchmark data (where available)*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL— HPO Path Volume II Quality management- Management System.**(QM003) (Each lab must have evidence of key quality indicators (i.e. hand hygiene & specimen identification) as source of quality indicators.** *Occurrence management **HERO *Hopkins Event Reporting Online* * Hospital event system - Departmental Quality Improvement Report Card (QM016)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3577/policy_3577.pdf	https://hpo.johnshopkins.edu/hopkins/policies/68/22702/policy_22702.pdf?_=0.271656776058
GEN.20316 R		**cont . QM Indicators of Quality** The QM program include monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases by regularly comparing performance against targets defined by the laboratory.	● Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents. ● Corrected Reports – General Laboratory : Percent of reports that are corrected. ● Amended Reports – Anatomic Pathology : Percent of reports that are ammend. ● Surgical Pathology/Cytology Specimen Labeling : Percent of requisitions or specimen containers with one or more errors of pre-defined type. ● Blood Component Wastage : Percent of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue. ● Blood Culture Contamination : Percent of blood cultures that grow bacteria that are highly likely to represent contaminants. ●Laboratory Test Utilization: Percent of tests (or a test) that appear to be redundant, excessive or noncontributory to good patient care. The CAP Quality Management Program tools (eg, Q-TRACKS and Q-probes) and publications through the Archives of Pathology provide information regarding definitions of quality indicators and demonstrate statistically valid peer-group performance standards. Publications can be downloaded from cap.org at the following link: https://www.cap.org/laboratory-improvement/quality-management-programs +++ For benchmark information on commonly used quality indicators, please refer to the Quality Management Quality Indicator Monitoring Guidance Document posted on the CAP website at the following link: ***Quality Management Quality Indicator Monitor Guidance***		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL— HPO Path Volume II - Quality management-Quality Management program (Division Quality Plans)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3577/policy_3577.pdf	Each lab must have evidence of key quality indicators (i.e. hand hygiene & specimen identification)
GEN.20318 N	2	**Corrective and Preventive Action** The QM program includes processes for recording corrective and preventive actions taken for errors and incidents (ie, non-conforming events) and quality indicators that do not meet defined targets, and evaluating the effectiveness of the actions taken.		*✓Records of corrective and preventative actions and effectiveness evaluation*			
GEN.20320 R	2	**QM Indicators of Quality-*Biorepositories Only*** The QM program includes monitoring key indicators of quality by regularly comparing performance against targets defined by the biorepository.	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 must be consistent with the biorepository's scope of service.	*✓Listing of quality indicators that are appropriate for the scope of services AND* *✓Defined targets for evaluating quality indicator monitoring data AND* *✓Quality indicator monitoring against targets based on benchmark data (where available)*			
GEN.20325 R	2	**Employee and Patient Quality Communication** The quality management program includes a process for employees and patients to communicate quality and safety concerns to management.	**NOTE:** The investigation and analysis of employee and patient complaints and suggestions, with corrective or preventive action as appropriate, must be included in the laboratory quality management records.	*✓Records of employee complaints (if any) with appropriate follow up*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUALA— HPO Path Volume II- Quality management-Quality Management Program (Appendix C -section- III Responsibility)	https://hpo.johnshopkins.edu/hopkins/policies/39/36/policy_36.pdf?_=0.197646408996	Patient complaints are followed by the Patient Relations Department. Employee complaints are followed by way of communication/problem logs, division/laboratory chain of command ; compliance hotline, as well as HERO system

GEN.20326 replaced GEN. 10902	2	**Assessment of the QM Program Implementation** For laboratories that have been CAP accredited for more than 12 months, the QM program is implemented as designed.and is assessed at least annually for effectiveness	**NOTE:** The QM program must include an appraisal of the following activities: ● Performance of quality indicators ● Effectiveness of actions taken when quality indicators do not meet targets ● Follow-up of issues, including non-conformances, requiring corrective/preventive action ● Actions taken when concerns about quality and safety are reported The laboratory must determine if quality indicators are retained/retired on the basis of the performance, criticality, and effectivenessmayof any corrective/preventive measures taken and select new monitors based on current or potential care and quality concerns. Recording of the assessment of the QM program can be achieved by different mechanisms, such as an annual written report, or quality management committee meeting minutes. Results of the assessment must be communicated to , appropriate laboratory personnel and key stakeholders.	*✓Records of effectiveness assessment AND* *✓Evaluation of quality measurements AND* *✓Records of communication of assessment results with appropriate personnel and key stakeholders*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–– HPO Path Volume II– Quality management– Management Program.**QM002** Quality Management Plan Policy-**QM017**	Quality Management program	Each lab must have evidence of Quality Management Plan implementation as designed// ***copy link to browser*** https://hpo.johnshopkins.edu/hopkins/policies/68/30846/policy_30846.pdf?_=0.829028856322
GEN.20327 R	2	**Quality Communication - Biorepositories Only** The quality management program includes a process for employees, participants, and researchers to communicate quality, safety, and research misconduct concerns to management.	NOTE: The investigation and analysis of employee, participant, and researcher complaints and suggestions, with corrective or preventive action as appropriate, must be included in the biorepository quality management records.	*✓Records of employee, participant, and researcher complaints (if any) with appropriate follow up*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–– HPO Path Volume II - Quality management-Quality Management Program (Appendix C -section- III Responsibility)	https://hpo.johnshopkins.edu/hopkins/policies/39/36/policy_36.pdf?_=0.19764048996	Patient complaints are followed by the Patient Relations Department. Employee complaints are followed by way of communication/problem logs, division/laboratory chain of command ; compliance hotline, as well as HERO system
GEN.20330 R	2	**CAP Sign** The laboratory posts the official CAP sign regarding the reporting of quality concerns to the CAP in a prominent location in the laboratory.	**NOTE:** The sign is intended to be placed in a location where it will be available to personnel. It is not a requirement to post the CAP sign in patient care areas. While personnel should report concerns to laboratory management, the laboratory must ensure that all personnel know that they may communicate with the CAP directly if they have a concern not addressed by laboratory management, and that the CAP holds such communications in strict confidence. In addition, the laboratory must have a policy prohibiting harassment or punitive action against an employee in response to a complaint or concern made to the CAP or other regulatory organization regarding laboratory quality or safety. Laboratories new to the CAP's accreditation programs (not yet accredited) receive a temporary sign after completion of the online application process, which must be posted upon receipt. After laboratories are accredited, they are awarded with the official sign for CAP-accredited laboratories to replace the temporary sign. The dedicated, confidential CAP telephone lines for quality or safety concerns are 866-236-7212 (US, toll-free) and 847-832-7533 (international). *Additional CAP signs may be obtained by contacting the CAP at* 800-323-4040		Each lab area must post the CAP poster. (CAP phone -line for Quality and safety concerns), to include the Reporting Quality and Safety concern addendum. ∞ CAP phone line for Quality or Safety Concerns	http://www.cap.org/apps/docs/laboratory_accreditation/build/pdf/08WhistleBlowerSAEN.pdf	http://pathology.jhu.edu/campus/Reporting_Quality_Concerns_new.pdf
GEN.20335	1	**Customer Satisfaction** The laboratory has measured the satisfaction of clients (eg, healthcare providers, patients, referring laboratories, nurses) with laboratory services within the past two-years.	**NOTE:** Satisfaction metrics are important for understanding the needs of clients to improve laboratory services. Experience has shown that surveys are more informative if they are conducted anonymously and allow for open ended comments. The sample size should be adequate. A numeric satisfaction scale allows for calculation of statistics.	*✓Records of the design and results of satisfaction surveys*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–A-Administrative-1a–– HPO Path Volume II - Quality management-Quality Management System (Assessment External/Internal)	http://www.insidehopkinsmedicine.org/hpo/policies/08/3578/policy_3578.pdf	Ex. HERO phlebotomy physician surveys
GEN.20340	2	**Notifications From Vendors** The laboratory manages notifications from vendors of defects or issues with reagents, supplies, instruments, equipment, or software that may affect patient care/client services.	**NOTE:** Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory should take timely action on those that have the potential to affect testing results or laboratory services.	*✓Written policy for the handling of recalls and notifications AND* *✓Records of manufacturer's recalls received AND* *✓Records of Follow-up*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–– HPO Path Volume II - Operation: Laboratory Equipment Management and Adverse Reporting Policy (OPER002) : VII Hasard or recall notices- pg. 3	https://hpo.johnshopkins.edu/hopkins/policies/68/4263/policy_4263.pdf?_=0.3638247549 11	
GEN.20351	2	**Advense Patient Event Reporting** The laboratory has a procedure for reporting device-related adverse patient events, as required by the FDA.	**NOTE:** When information reasonably suggests that any laboratory instrument, reagent or other device (including all instruments in the central laboratory, satellite laboratories, point-of-care testing programs, and accessory devices used for phlebotomy or specimen collection) has or may have caused or contributed to a patient death or serious patient injury, the FDA requires hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report must be made both to the FDA and the device manufacturer. If the event is serious patient injury, the report may be to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA. Reports must be submitted on the FDA Form 3500A (or an electronic equivalent) as soon as practicable but no later than 10 days from the time medical personnel become aware of the event. This checklist item does NOT apply to laboratories accredited under the CAP Forensic Drug Testing program. Compliance with this checklist item is voluntary for non-U.S. laboratories. The FDA defines "serious patient injury" as one that is life threatening; or results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling*, reagents or calibration; or to user error (since the latter may be related to faulty instrument instructions or design). An adverse patient event that may have resulted from inherent limitations in an analytic system (e.g., limitations of sensitivity, specificity, accuracy, and precision) is not reportable. The laboratory should have written procedures for 1) the identification and evaluation of adverse patient events, 2) the timely submission of MDR (medical device reporting) reports, and 3) compliance with record keeping requirements.	*✓Records of MDR reports for reportable events, if applicable*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–– HPO Path Volume II - Operation: Laboratory Equipment Management and Adverse Reporting Policy (OPER002) IMSMAS : IV Hasard or recall notices- pg. 1-2, FDA Reporting Institutional Recall Management and Reporting MEL023	http://www.insidehopkinsmedicine.org/hpo/policies/68/4263/policy_4263.pdf	https://hpo.johnshopkins.edu/hopkins/policies/39/6557/policy_6557.pdf?_=0.293490967034
GEN.20351	2	**Advense Patient Event Reporting. (continuation)**	A written record of participation in the overall institutional MDR process is required of laboratories that are part of a larger organization (e.g. hospital laboratories). The laboratory should educate its personnel in the FDA MDR requirements. The laboratory (or parent institution, as appropriate) must submit an annual report of device-related deaths and serious injuries to FDA, if any such event was reported during the previous year. Annual reports must be submitted on Form 3419 (for hospital based laboratories only, or an electronic equivalent) or Form 3500 (for non- hospital based laboratories) by January 1 of each year. The laboratory or institution must keep records of MDR reports for 2 years. Additional information is available on the FDA website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm *In this context, "labeling" refers to all user instructions provided by the manufacturer.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL–– HPO Path Volume II - Environment :: Equipment Policy: VII Reportable conditions- Pg. 3	http://www.insidehopkinsmedicine.org/hpo/policies/68/4263/policy_4263.pdf	

GEN.20361	2	**CLIA Certificate Type** For laboratories subject to US regulations performing patient testing subject to CLIA, the laboratory has registered with the Centers for Medicare and Medicaid Services (CMS) and obtained a CLIA certificate that corresponds to the complexity of testing performed, as applicable**.**	**NOTE:** This requirement does not apply to laboratories that are part of the Department of Defense. Laboratories located in CLIA exempt states, such as Washington and New York, must be able to show that they have obtained a CLIA number, when appropriate. The CLIA regulations define a laboratory as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Examples of laboratory activities that do not require registration with the CMS for a CLIA number include: ● Specimen collection ● Specimen preparation, including histology, tissue embedding, sectioning, and staining ● Forensic testing ● Research testing on human specimens where patient-specific results are not reported to the clinician ● Drug testing meeting SAMHSA guidelines and regulations Laboratories must obtain the CLIA certificate type that corresponds to their highest level of complexity. The CLIA certificate types include: ● Certificate of Waiver - waived tests only* ● Certificate of Provider Performed Microscopy (PPM) Procedures - testing performed by a physician, midlevel practitioner or dentist for specific microscopy procedures (moderate complexity) during the course of a patient's visit ● Certificate of Registration - nonwaived testing (moderate or high complexity) prior to initial laboratory inspection		Contact CQI Office for Clarification if needed		
cont. GEN.20361	2	**CLIA Certificate Type**	● Certificate of Compliance - nonwaived testing with inspection by the State Department of Health (CLIA inspection) ● Certificate of Accreditation - nonwaived testing with inspection by a CMS-approved accrediting organization, such as the CAP's accreditation programs. For more information on the CMS requirements for CLIA certificates and types of CLIA certificates, refer to Appendix C of the CMS Interpretive Guidelines for Laboratories **(http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html)**. **Any modification from the manufacturer's instructions changes the test classification to nonwaived and requires a different type of CLIA certificate.*		Contact CQI Office for Clarification if needed	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	
GEN.20374 R	1	***Natinol/ Federal /State/Local Regulations*** The laboratory has a policy for ensuring compliance with applicable **national**, federal**,** state **(or provincial)** and local laws and regulations.	**NOTE:** Applicable **national**, federal, state **(or provincial)** and local requirements may include but are not limited to the following areas: ● Tissue handling ● Handling radioactive materials. ● Shipping infectious or diagnostic materials. ● Reporting infectious disease testing results. ● Personnel qualifications. ● Retention of specimens and records ● Hazardous waste disposal, storage of flammable materials. ● Fire codes. ● Medical examiner or coroner jurisdiction. ● Legal testing. ● Acceptance of specimens only from authorized personnel. ● Handling controlled substances. ● Patient consent for testing. ● Confidentiality of test results. ● Donation of blood. The checklists contain specific questions on these areas. ' For biorepositories, laws and regulations may also include, as applicable: ● Storage and handling of select agents ● Storage of bulk fuels and other hazardous materials (eg, diesel and liquid nitrogen) ● Use of material transfer agreements. The laboratory may obtain information on applicable laws and regulations from multiple sources, including hospital management, state medical societies and state departments of health.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-1b-== HPO Path Volume II - Quality Management System (Organization- Federal /State/Local Regulations)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3578/policy_3578.pdf	
GEN.20375	2	**Document Control** The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation.	**NOTE:** This includes documents relating directly to laboratory testing, as well as others, such as quality management, safety, specimen collection, personnel, and laboratory information systems. The document control system must ensure that only current policy, procedures ,(including derivative documents such as card files charts or similar systems that summarize key information for quick reference at the workbench) and forms are in use and that records for approval, review, and discontinuance are available. ***Discontinued documents must be appropriately archived and removed from general access.*** ***The document master files must be securely stored in a manner that prevents loss, damage, or unauthorized access. Documents needed for functioning of the laboratory must be backed up in a manner that allows access to authorized users in case of power or network system outages (eg, paper-based system or electronic system with emergency power).*** It is recommended that the laboratory maintain a control log listing all current policies, procedures, and forms with the locations of copies. The control log may contain other information as appropriate, such as dates when policies and procedures were placed in service, schedule of review, identity of reviewer(s), and dates when policies and procedures were discontinue and or superseded. Additional requirements regarding procedure manuals are found in the All Common Checklist, and in this checklist in the Collection Manual, Computer Services and Safety sections.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-1b-== HPO Path Volume II-Pathology HPO Management Policy (ADM013)	https://hpo.johnshopkins.edu/hopkins/policies/68/10572/policy_10572.pdf?_=0.113871274335	http://www.insidehopkinsmedicine.org/hpo/policies/68/3901/policy_3901.pdf
GEN.20377 R	2	**Record/Specimen Retention** Laboratory records and materials are retained for an appropriate time.	**NOTE:** Policies for retention of records and materials must comply with **national**, federal, state **(or provincial)**, and local laws and regulations and with the minimum retention periods listed below, whichever is most stringent. For testing on minors (under the age of 21), stricter state regulations may apply. More specific requirements for certain laboratory records are found in the Anatomic Pathology **(ANP.12500, ANP.23670, ANP.33500, ANP.36125), Biorepository (BAP.13740),** Cytopathology **(CYP.06600, CYP.06900)**, Cytogenetics **(CYG.32700), Flow Cytometry (FLO.23700)**, Molecular Pathology **(MOL.35870,MOL.49640)** , Reproductive Laboratory Medicine **(RLM.12466),** and Transfusion Medicine Checklists **(TRM.32250)**. **see Retention Table** * Laboratories may wish to retain instrument maintenance records for longer than the two-year requirement (e.g. for the life of the instrument), to facilitate trouble-shooting ** For data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years. Manual computer entry of patient result data from worksheets, print-outs, etc. requires retention of all worksheets, printouts, etc. for at least two years (digitized or photographic images are acceptable). For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer.	✓*Written policy for retention of records, specimens and slides*	DEPARTMENT OF PATHOLOGY Volume II - General Policy Manual-Documents and Records, Record and Material Retention Policy (ADM005)	https://hpo.johnshopkins.edu/hopkins/policies/68/4266/policy_4266.pdf?_=0.635945546672	See appendix A in Policy
GEN.20425	2	**Record Retention** The laboratory has a policy to ensure that all records, slides, blocks, and tissues are retained and available for appropriate times should the laboratory cease operation.			DEPARTMENT OF PATHOLOGY Volume II - General Policy Manual-Documents and Records, Record and Material Retention Policy (ADM005)	http://www.insidehopkinsmedicine.org/hpo/policies/68/4266/policy_4266.pdf	
GEN.20430 N	2	**Verification of Copies of Records Prior to Destruction.** There is a written procedure to ensure that laboratory records (eg, patient reports, worksheets, quality control records) being converted onto another medium for storage and retention are verified for accuracy, legibility, and completeness before the original record is destroyed.					
GEN.20450	2	**Correction of Laboratory Records** The laboratory follows a written policy for the management and correction of laboratory records, including quality control data, temperature logs, and intermediate test results or worksheets.	**NOTE:** Laboratory records and changes to such records must be legible and indelible. Original (erroneous) entries must be visible (i.e. erasures, white and correction fluid are unacceptable) or accessible (e.g. audit trail for electronic records). Corrected date, including the identity of the person changing the record and when the record was changed, must be accessible to audit. This requirement does not apply to changes to patient reports (refer to GEN.41310).	✓*Records of corrections to laboratory records following the policy*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-HPO Path Volume II-QM003-Quality Management Systems -0<--==Documents and records - Correction of laboratory records.	https://hpo.johnshopkins.edu/hopkins/policies/68/3578/policy_3578.pdf?_=0.491211162361	

GEN.23584	2	**Interim Self-Inspection** The laboratory has conducted a thorough interim self-inspection and has corrected all deficiencies.	**NOTE:** CAP-accredited laboratories are required to complete an interim self inspection at the start of the second year of the laboratory's two-year accreditation cycle. It is an important aspect of continuing education laboratory improvement, and continuous compliance. Laboratories must retain records of the CAP self-inspection , as well as the corrective action for deficiencies , as part of the quality management program. The laboratory director's signature on the CAP's Self-Inspection Verification form alone is not sufficient to meet this requirement .	✓*Written evidence of self-inspection findings with records of corrective action*	Each laboratory must complete a thorough interim self-inspection and submit deficiency findings with records of corrective action.		
GEN.26791 R	2	**Terms of Accreditation** The laboratory has a **written** policy that addresses compliance with the CAP terms of accreditation	**NOTE:** The CAP terms of accreditation are listed in the laboratory's official notification of accreditation. The **written** policy must include Cooperation in any CAP investigation or inspection and prompt notification to the CAP ◊ If the laboratory becomes the subject of: • An investigation by a government entity (including national, federal, state (or provincial), local, or foreign)or other oversight agency. • A validation inspection. • Adverse media attention relating to laboratory performance. ◊ Prompt notification to the CAP: • If the laboratory discovers laboratory personnel actions that appear to violate national, state (or provincial), or local laws that regulates laboratories. • Of any changes in laboratory activity menu prior to beginning that testing or implementing scope of service changes, or the lagboratory permanenetly or temporarily discontinues some or all testing. • Of any changes in directorship, location, ownership, name, insolvency, or bankruptcy in the 10 days prior to the change; or, in the case of unexpected changes, no later than 2 working days afterwards. Laboratories subject to the US CLIA regulations must also notify the CMS of pertinent changes.	✓*Records of notification, if applicable*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-O-— HPO Path Volume II CAP Terms of Accreditation.	https://hpo.johnshopkins.edu/hopkins/policies/68/4183/policy_4183.pdf	
GEN.26791 R		**cont,Terms of Accreditation** The laboratory has a **written** policy that addresses compliance with the CAP terms of accreditation	◊ Provision of a trained inspection team comparable in size and scope to that required for its own inspection during the two-year accreditation period, if requested by the regional and/or state commissioner. ◊ If the laboratory is subject to the Us CLIA regulations: • Availability on a reasonable basis, the laboratory's annual PT results upon request of any person • Provision to allow the CMS or its agent to perform a validation or complaint inspection at any time during the laboratory's hours of operations and permit the CMS to monitor the correction of any deficiencies found during such an inspection. ◊ Adherence to the Certificate Mark Terms of Use/Agreement for the CAP Certification Mark and Design if the laboratory is/or will use the CAP Certification Mark for accreditation. The agreement can be downloaded and printed from cap.org.	✓*Records of notification, if applicable*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-O-— HPO Path Volume II CAP Terms of Accreditation.	https://hpo.johnshopkins.edu/hopkins/policies/68/4183/policy_4183.pdf	
GEN.30000	2	**Monitoring Analytic Performance** There is a written quality control program that clearly defines policies and procedures for monitoring analytic performance.	NOTE: There must be a written overall quality control program for the entire laboratory. It must include general policies and assignment of responsibilities. There must be clearly defined, written procedures for ongoing monitoring of analytic performance, including: ● Number and frequency of controls; ● Establishment of tolerance limits for control testing; and ● Corrective actions based on quality control data. Quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director, supervisor or laboratory quality control coordinator).		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-— HPO Path Volume II: Quality Management (VIII Process Management)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3578/policy_3578.pdf	Each division must have a specific quality control program to include verification of accuracy & precision.
			SPECIMEN COLLECTION, HANDLING, AND REPORTING				
			SPECIMEN COLLECTION INTRUCTIONS				
GEN.40016	2	**Specimen Collection Procedure Review** There are records of review of the specimen collection/handling procedure manual by the current laboratory director or designee at least every two years.					Each laboratory must have documentation of annual review.
GEN.40032	2	**New Specimen Collection Procedure Review** The laboratory director reviews and approves all new specimen collection and handling procedures, as well as substantial changes to existing procedures before implementation.	NOTE: Current practice must match written procedures.				
GEN.40050	1	**Distribution of Manuals** The specimen collection manual is distributed to all specimen-collecting areas within the hospital (nursing stations, operating room, emergency room, out-patient areas) AND to areas outside the main laboratory (such as physicians' offices or other laboratories).	NOTE: It is acceptable for this information to be electronically available to users rather than in book format; there is no requirement for a paper-based specimen collection manual. Indeed, electronic manuals have the advantage of more accurately reflecting current requirements.		Johns Hopkins Medical Laboratories Services	http://pathology.jhu.edu/departments/services/labservices.cfm	
GEN.40100	2	**Specimen Collection Manual Elements** The specimen collection manual includes instructions for all of the following elements, as applicable. 1. Preparation of the patient 2. Type of collection container and amount of specimen to be collected 3. Need for special timing for collection (e.g., creatinine clearance) 4. Types and amounts of preservatives or anticoagulants 5. Need for special handling between time of collection and time received by the laboratory (e.g., refrigeration, immediate delivery) 6. Proper specimen labeling 7. Need for appropriate clinical data, when indicated	NOTE: Because of the importance of clinical information in the practice of surgical pathology and cytopathology, requisitions for such specimens should include pertinent clinical data, as well as pre-operative and/or post-operative diagnosis. Written instructions should be available for all applicable tissue and cytologic specimens, including biopsies, resections, PAP tests, sputum washings, brushings, body fluids, fine needle aspirations, etc. Instructions must include proper fixation of slides and tissue specimens. A variety of tests in clinical pathology also require specific clinical information (e.g. maternal AFP screening, TDM peak and trough measurements, and antibiotic therapy) or special instructions for collection, preservation, and storage (e.g. timed or 24-hour urine specimens). Instructions for the collection of blood specimens for alcohol testing must include proper skin preparation and the use of appropriate preservatives.		Johns Hopkins Medical Laboratories Services	http://pathology.jhu.edu/departments/services/labservices.cfm	
GEN.40125	2	**Handling of Referred Specimens** For specimens sent to referral laboratories, the referring laboratory properly follows all requisition, collection and handling specifications of the referral laboratory.	NOTE: Preanalytic variables must be closely controlled to maintain specimen integrity. These include specimen temperature, transport time, and the interval before separation of blood cells from serum/plasma. It may also necessary to collect specific patient information required by the testing laboratory (e.g.clinical information for cytopathology, and surgical pathology, gestational age for prenatal neural tube defect screening, bleeding history for specialized coagulation assays). Laboratories must follow specific collection requirements for the following types of testing: ● Coagulation - proper filling of the collecton tube, the use of waste tubes, and flushing of lines, if blood is drawn through an indwelling line ● Surgical pathology and cytopathology - preservation of specimens by proper fixation or refrigeration. For breast tissue pathology specimens removed for lesions clinically suspicious for malignancy, the cold ischemia time (time of removal of the tissue from the patient to time placed in fixative) and total fixation time must be recorded and submitted to the referral laboratory. ● Twenty-four-hour urine testing - special preservatives for specific tests. ● Microbiology -timing of specimen collection, collection techniques, and selection of appropriate collecton devices and transport media. ● Newborn screening specimen collection, application and drying of blood spots, and submission of specimens to the referral laboratory . The designated newborn screening laboratory's instructions must be followed and be in compliance with the most recent edition of the CLSI Document NBS01 and state or local regulations. Specimens must be transported after they are dry and no later than 24 hours after collection or following the instructions provided by the designated newborn screening laboratory. Delays in specimen transportation from the collection facility to the testing laboratory may compromise the integrity of the specimen and results and could critically impact the newborn.	✓*Written procedure for submission of specimens to referral laboratories, consistent with the referral laboratory collection and handling requirements*	Johns Hopkins Medical Laboratories Services DEPARTMENT OF PATHOLOGY Volume II - General Policy Manual-Pathology Referal Laboratory Services ADM004	https://hpo.johnshopkins.edu/hopkins/policies/68/4243/policy_4243.pdf?_=0.8350388409781	https://hpo.johnshopkins.edu/hopkins/policies/39/11214/policy_11214.pdf?_=0.8700438623831

cont. GEN.40125	2	Handling of Referred Specimens	For newborn screening specimens, the specimen collection, application and drying of blood spots, and submission of specimens to the referral laboratory must follow the designated newborn screening laboratory's instructions and be in compliance with the most recent edition of the CLSI Document NB 501 and state or local regulations. Specimens should be transported after they are dry and no later than 24 hours after collection or following the instructions provided by the designated newborn screening laboratory. Delays in specimen transportation from the collection facility to the testing laboratory may compromise the integrity of the specimen and results and could critically impact the newborn.				
GEN.40140	2	**Handling of Referred Laboratory Specimens - Biorepositories Only** For specimens sent to referral laboratories, the referring laboratory properly follows all requisition, collection and handling specifications of the referral laboratory.	NOTE: Pre-analytic variables must be closely controlled to maintain specimen integrity. Critical pre-analytic variables to be tracked include those conditions that will have a significant effect on the quality of the specimen in the performance of the indicated testing. The laboratory must document the acceptable and unacceptable pre-analytical conditions for the use of specimens specific to the methods of testing.	*✓Written procedure for submission of specimens to referral laboratories, consistent with the referral laboratory collection and handling requirements*			
			SPECIMEN COLLECTION AND LABELING				
			Accurate and precise laboratory data are dependent on properly collected clinical specimens.				
GEN.40460	1	**Specimen Collection Supplies** Specimen collection supplies such as blood collection tubes and collection devices (e.g. heel lancets, culture swabs, and transport media) are used within their expiration date and stored per manufacturer's instructions.	NOTE: For newborn screening collection cards, if the expiration date is not printed on the individual cards, another mechanism, such as serial number, may be used for tracking.				
GEN.40470	2	**Specimen Collection Training** There are records that all personnel collecting specimens have been trained in collection techniques and in the proper selection and use of equipment/supplies and are knowledgeable about the contents of the specimen collection procedures..	NOTE: This applies to laboratory personnel, including those at remote sites that are owned and operated by the laboratory. It applies to all personnel who collect and test samples under the laboratory's CAP number, such as for point-of-care testing and for blood gas analysis. It does not apply to the collection of specimens sent to the laboratory by hospital personnel or from outside sources. All types of specimen collection techniques (e.g. phlebotomy, capillary, arterial, in-dwelling line, phlebotomy during intravenous infusion), as well as non-blood specimens, must be included in the training in accord with the individuals' duties. If the laboratory uses prepackaged kits for specimen collection, any special instructions that accompany the kit must be part of the training.				
GEN.40490	2	**Patient Identification** The individual collecting the specimen positively identifies the patient before collecting a specimen and labels the specimen in the presence of the patient.	NOTE: Personnel must confirm the patient's identity by checking at least two identifiers before collecting a specimen. For example, an inpatient's wristband may be checked for name and unique hospital number; an outpatient's name and birth date may be used. The patient's room number may not be used as an identifier. The patient's identity should be verified by asking the patient to identify him- or herself, when it is practical to do so*. The intent of this question is to ensure a written, consistently followed system for correct patient and specimen identification at the point of collection. *For example, verbal verification is not necessary if obtaining the services of a translator would delay specimen collection.	*✓Written collection procedure including criteria for patient identification*	**ICPM**-Identification of Patients	http://www.insidehopkinsmedicine.org/hpp/policies/39/72/policy_12.pdf	
GEN.40491	2	**Primary specimen container Labeling** All primary specimen containers are labeled with at least two patient-specific identifiers	NOTE: A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage. Data files received from other laboratories for analysis are considered a specimen and must contain acceptable patient identifiers. Criteria for acceptable specimen labeling and the handling of sub-optimal specimens must be defined in laboratory policy. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, social security number, requisition number, accession number, unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Identifiers may be in a machine readable format, such as a barcode. In limited situations, a single identifier may be used if it can uniquely identify the specimen. For example, in a trauma situation where a patient's identification is not known, a specimen may be submitted for testing labeled with a unique code that is traceable to the trauma patient. Other examples may include forensic specimens, coded or de-identified research specimens, or donor specimens labeled with a unique code decryptable only by the submitting location. Obtaining uniform compliance with this requirement may be difficult when specimens are collected by non- laboratory personnel. The laboratory should **1.** Provide a list of acceptable identifiers to all specimen collectors; **2.** Communicate with specimen collectors regarding the importance of this requirement; and **3.** Have a procedure for following up with specimen collectors when inadequately labeled specimens are received. Communication and follow-up may be through QM reports, written memoranda, phone calls, visits by client service personnel, or other means of disclosure.	*✓Written policy with criteria for acceptable labeling of primary specimen containers AND ✓Specimen collection procedures with defined labeling specifications AND ✓Records of audits for compliance with specimen labeling policies and procedures*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-1b—► HPO Path Volume II-Customer Focus_ Misidentified or unidentified patient specimens (PS004), ICPM Misidentified of Unidentified Patient Specimen PAT027	http://www.insidehopkinsmedicine.org/hpp/policies/39/70/policy_70.pdf	
GEN.40492	2	**Specimen Label Correction** The laboratory has a written policy regarding correction of information on specimen labels.	NOTE: If laboratory personnel become aware of a potential error in patient identification or other information (eg., initials of individual collecting the specimen, date/time of collection) on a specimen label, best practice is to recollect the specimen. However, there may be circumstances when recollection is not possible or practical (eg., for specimens that are impossible or difficult to recollect, such as cerebrospinal fluid). The laboratory should define the circumstances under which correction of the information on specimen labels is permitted. A record of all such corrections should be retained. The laboratory should investigate errors in specimen labeling, and develop corrective action as appropriate, including education of personnel who collect specimens.	*✓Records of corrections to specimen labels and corrective action*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Administrative-1b—► HPO Path Volume II-Customer Focus-Misidentified or unidentified patient specimens (PS004)	http://www.insidehopkinsmedicine.org/hpp/policies/39/70/policy_70.pdf	
GEN.40493	2	**Specimen Labeling *for Pretransfusion Testing.*** All blood specimens collected for ***pretransfusion*** testing are labeled at the time of specimen collection with: 1. Patient's first and last name 2. Unique identification number 3. The date of collection 4. A method to identify the individual collecting the specimens	NOTE: Blood specimens collected for compatibility testing must be positively and completely identified and labeled before leaving the patient. Acceptable practices for positive identification of patient and blood specimen labels must be defined in the procedure manual and may include visual inspection and/or an electronic system to read the identifying information contained in bar codes or radio-frequency identification (RFID) microchips or the patient's wristband. Acceptable practices for generating specimen labels must be defined in the procedure manual and may include electronic devices utilizing information encoded in bar codes or RFID microchips. There must be a dependable method to identify the individual who collected the blood specimen, such as initials or another identifier on the tube, or an electronic record.	*✓Written procedure defining labeling requirements of specimens for pretransfusion testing AND ✓Written procedure defining system identifying the individual collecting pretransfusion testing specimens*			
GEN.40495	2	**Relationship and Forensic Identity Testing Specimen Collection** Specimens collected for relationship and forensic identity testing are collected and processed meeting the following criteria: **1.** Collections are performed by an unbiased, third party individual with no interest in the outcome of the case. **2**. Collection materials are not in the possession of the tested parties at any time prior to, during, or following the collection procedure **3.** The specimens and accompanying documents are shipped to the testing laboratory directly by the collector.		*✓Policies and procedures for specimen collection*			
GEN.40497	2	**Relationship and Forensic Identity Testing Specimen CollectionData** For relationship and/or forensic identity testing, the following data are obtained during specimen collection for each person to be tested: 1. Printed name of person being tested 2. Alleged relationship, if applicable 3. Date of birth 4. Race/ethnic background with the exception of a child being tested 5. Place and date of specimen collection 6. Printed name, signature, and contact informationof person(s) collecting and/or witnessing (if different) the specimen collection. Photograph, or legible photocopy of a picture identification card for each individual tested 7. Government issued ID or other photograph suitable for positive identification 8.History of transfusion in the preceding three months or any history of allogeneic hematopoietic progenitor cell transplantation 9. Synopsis of case history/investigation, sample source, if applicable for forensic purposes 10. Record of informed consent from the individual being tested or individual with legal authority	NOTE: If the laboratory uses prepackaged kits for specimen collection, any additional instructions that accompany the kit must be followed	*✓Policies and procedures for specimen collection AND ✓Records of specimen collection for relationship and forensic identity testing*			

GEN.40498	2	**Relationship and Forensic Identity Testing specimen Labeling** For relationship and identity testing, information about each individual and the accuracy of the specimen label are verified by that individual or the legal guardian. The affixed label on each specimen contains the following: 1. At least two unique identifiers, such that each specimen can be unmistakably identified from other specimens in the same case. 2. Date of specimen collection 3. Initials or signature of the collector verifying the specimen integrity		*✓Records of information and label verification by patient or legal guardian*			
GEN.40499	1	**Specimen Collection Feedback**. There is a mechanism to provide feedback to the collectors of specimens on issues relating to specimen quality and labeling	NOTE: The accuracy of an analytic result depends upon the initial quality of the specimen. Proper collection techniques are essential.	*✓Written procedure defining methods for providing feedback to specimen collectors AND* *✓Records of communication of specimen collection issues, such as QM reports, staff meeting minutes OR records of employee counseling*			
GEN.40501	**2**	**Phlebotomy Adverse Reaction** The laboratory have procedures to care for patients who experience adverse reactions from phlebotomy.	NOTE: Minor adverse reactions include hematomas, abrasions, nausea, and fainting. Serious injuries include vomiting, nerve damage, seizures and injuries. Training of phlebotomists should emphasize injury prevention. Serious reactions must be recorded in an incident log.	*✓Written instructions to phlebotomists AND* *✓Training records*			
		CHAIN-OF-CUSTODY SPECIMEN COLLECTION AND HANDLING ***This section applies to laboratories using a chain-of-custody process for collection and/or processing of patient specimens intended for laboratory testing, including laboratories that refer testing to other laboratories or perform the testing on-site. If a chain-of-custody process is not used, this section is not applicable.*** ***Collection and testing performed for medical diagnosis and treatment does not require the use of a chain-ofcustody process. The need for a chain-of-custody process is determined by each laboratory based on its setting and services offered. If testing is to be performed following a chain-of-custody process, specimens must follow the chain-of-custody process for the entire process from beginning to the end.*** ***NOTE: This section does not apply to laboratories participating in the Reproductive Laboratory Accreditation Program or the Forensic Drug Testing Accreditation Program.***					
GEN.40502	**2**	**Chain-of-Custody Procedures** There are written procedures for chain-of-custody specimen collection, accessioning, and handling.	NOTE: If specimens are referred to another laboratory, the collection site must follow chain-of-custody instructions provided by the referral laboratory.				
GEN.40503	**2**	***Chain-of-Custody Records*** *The external and internal chain-of-custody records (as applicable) for specimen collection, receiving, accessioning, and handling are complete and include the following:* *● Type of specimen collected* *● Verification of patient and/or specimen identity* *● Identification of laboratory-generated aliquots* *● Verification of the integrity (tamper-evident) of the specimen container.* *● Identity of individuals handling the specimens* *● Storage location when not in the possession of an authorized individual, including aliquots* *●Reason for the transfer of custody and date of transfer*	*NOTE: If specimens are referred to another laboratory, the collection site must follow chain-of-custody instructions provided by the referral laboratory.*	*Evidence of Compliance:* *✓Written chain-of-custody procedure AND* *✓Completed chain-of-custody records following written procedure*			
GEN.40504	**2**	**Chain-of-Custody Acceptability Criteria** The chain-of-custody procedure defines criteria for determining the acceptability of specimens and the process followed when unacceptable specimens are identified (i.e. reporting problems to the client).	NOTE: Clients and laboratories may have different rules for evaluating a specimen for its acceptability for analysis (chain-of-custody failures, missing information, specimen leakage, inadequate volume, wrong type of specimen submitted, etc.). Unacceptable specimens must be monitored by the laboratory as part of its quality management program.	*Evidence of Compliance:* *✓Specimen rejection records*			
GEN.40506	**2**	**Secured Specimen Storage** The original specimens (in the original container) and appropriately labeled aliquots are maintained in an appropriate manner when not in the possession of an authorized individual.	**NOTE**: The original specimens must always be maintained either in the direct custody of an authorized individual or be in a locked secured area accessible only to authorized individuals. This locked and limited-access area may be a refrigerator, freezer, or storage room within the laboratory. Aliquots or extracts in the laboratory for testing must be in the possession of an authorized individual or be maintained with "line of sight" custody. If the laboratory is a secure, limited access facility, custody of the aliquot may be assigned to an instrument or temporary storage area, as long as records of individual access and egress from the area are recorded. An authorized individual is considered a person with specific training and work responsibilities for chain-of-custody specimens. General personnel, such as custodians, or technologists not assigned to the chain-of-custody work, must not have unescorted access to secure areas.	*Evidence of Compliance:* *✓Written policy defining criteria for storage of and access to specimens collected by chain-of-custody procedures AND* *✓Records for internal chain-of-custody reflecting limited-access storage OR record of direct custody of the specimen by an authorized person at all times*			
GEN.40507	**2**	**Specimen Retention and Storage** Specimen retention and storage conditions are defined for each type of specimen tested by the laboratory using a chain-of-custody procedure.	NOTE: The minimum specimen retention time and storage condition must be defined in laboratory policy and comply with applicable laws and regulations.				
GEN.40509	**2**	**Secured Records** The chain-of-custody collection records, security logs, and testing records are retained for an appropriate period of time, no less than two years and following applicable laws and regulations, in a limited-access, secured (locked) area that is only accessible to authorized laboratory personnel.	NOTE: The laboratory must be able to store these records as long as any legal action is pending and following client/agency requests.	*Evidence of Compliance:* *✓Written policy addressing restricted access to secured records AND* *✓Written record retention policy*			
			SPECIMEN TRANSPORT AND TRACKING *This section applies to laboratories that send specimens to referral or other laboratories for testing, whether or not the specimen collection is performed by the laboratory staff. It also applies to referral laboratories that receive specimens from other laboratories or remote locations outside of the facility for testing.* *While transportation of clinical specimens may not be the responsibility of personnel under the control of the laboratory director, issues of tracking and specimen quality must be addressed to ensure quality laboratory results.*				
GEN.40511	2	**Specimen Tracking/Labeling** All specimens are properly packaged and labeled to indicate the general nature of the materials transported.		*✓Written procedure defining criteria for packaging and labeling*			
GEN.40512	2	**Infectious Material Packing/Shipping** The laboratory package and ship infectious material in accordance with applicable federal, state and local regulations.		*✓Written procedures for packaging and shipping that comply with regulations*	Health and safety training - DOT/IATA Dangerous Goods shipping	http://www.hopkinsmedicine.org/dhse/training/class_description/web	Each Laboratory shipping infectious materials must have documentation available for review .
GEN.40515	2	**Transport Personnel Training** transport personnel are trained in appropriate safety and packaging procedures suitable to specimen type and distances transported, including training for personnel involved in packaging and shipping infectious substances.	NOTE: Training should include issues such as adherence to regulations for transport of biohazards, use of rigid containers where appropriate, temperature control, notification procedures in case of accident or spills, etc. All personnel who package infectious specimens for shipment must satisfactorily complete training in these requirements. Federal and international regulations. mandate the proper packaging and transportation of infectious substances, also termed "etiologic agents." It is the laboratory's responsibility to determine whether specimens that are to be shipped are subject to the regulations, or are exempt. Specific requirements are set forth by the US Public Health Service, the US Department of Transportation and the US Postal Service. These apply to domestic transportation by land, air or sea, and to international air transportation. Certified training is required every 3 years. The laboratory should check with its local department of transportation or state health department for any recent revisions to these requirements. Laboratories outside of the US must comply with their national **state or provincial, or local laws and** regulations. ***These requirements for packaging and shipping of infectious substances do not apply to private couriers .*** The laboratory may send personnel to courses for certified training, or may obtain materials to train its personnel in-house. Resources for certified training are available from many sources, including state health departments, vendors of shipping materials, and the CDC National Laboratory Training Network (NLTN).	*✓Records of training for all personnel involved in transport of specimens*	Health and safety training - DOT/IATA Dangerous Goods shipping	http://www.hopkinsmedicine.org/hse/training/	Training records must be available for review

GEN.40530	2	**Specimen Tracking** For specimens submitted to the laboratory from remote sites, there is a tracking system and record to ensure that all specimens are actually received.	NOTE: Records should include time of dispatch and receipt, as well as condition of specimens upon receipt. An example of an acceptable tracking system is submission of a packing list (prepared by the client or courier) with each batch of client specimens, which may be checked against the specimens received by the laboratory. Some laboratory tests (e.g. coagulation assays) have limitations on time and temperature conditions between collection and analysis. This requirement applies to couriers/transportation systems that are within the laboratory organization or are contracted by it. It does not apply to couriers unrelated to the laboratory.	✓*Specimen shipping/transport logs AND* ✓*Records of follow up for specimens not received*			
GEN.40535	1	**Specimen Transport QM** There is a process for monitoring the quality of submitted specimens, correcting problems identified in specimen transportation, and improving performance of clients or ***sites*** that frequently submit specimens improperly.		✓*Records of corrective action OR communications with clients that frequently submit specimens incorrectly*			
GEN.40545	1	**Newborn Screening specimen Tracking** For specimens being submitted to a remote testing laboratory for newborn screening for congenital disorders, there is a tracking system and records to ensure that all specimens are submitted in compliance with timing requirements and that a result or other appropriate notification is received indicating that the specimens were actually received.	NOTE: Tracking records should include time of dispatch and condition of specimens upon submission. An example of an acceptable tracking system is the use of a packing list (prepared by the submitting site or courier) with each batch of specimens that is checked against the specimens received by the remote testing laboratory. Newborn screening laboratory specimens have limitations with time and humidity conditions between collection and analysis. This requirement applies to couriers/transportation systems that are part of the laboratory organization and to outside courier systems.	✓*Records showing results/notifications received on all specimens AND* ✓*Records of follow up for specimens not received at the remote laboratory*			
			REQUISITIONS AND SPECIMEN RECEIPT / HANDLING / PROCESSING				
GEN.40700	2	**Requisitions** All specimens are accompanied by an adequate requisition.	NOTE: In computerized settings, there may not be a paper requisition that is physically attached to the specimen container.				
GEN.40725	2	**Requisition Data Entry** Test requisition data elements are entered accurately into the laboratory information or record system.	NOTE: Data elements include patient demographic data; the name and location of the individual or entity ordering the test, as well as other elements needed for the final report (see GEN.41096). The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries. For test orders crossing an interface to the LIS, requirements for interface integrity apply.				
GEN.40750	2	**Requisition Elements** The paper or electronic requisition include all of the following elements, as applicable. 1. Adequate patient identification information (e.g., name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists) 2. Patient sex 3. Patient date of birth or age 4. Name and address (if different than the receiving laboratory) of the physician, legally authorized person ordering the test, or name and address of the laboratory referring the specimen 5. Tests requested 6. Last menstrual period (for gynecologic specimens) 7. ***Date*** of specimen collection, ***and if*** appropriate, ***time of collection.*** 8. Source of specimen, when appropriate 9. Clinical information, when appropriate	NOTE: Specimen source may be particularly important for microbiology, surgical pathology and cytopathology specimens. Surgical pathology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed. The patient's chart or medical record may be used as the test requisition or authorization.				
GEN.40825	2	**Specimen ID** There is a system to positively identify all patient specimens, specimen types, and aliquots at all times	NOTE: Each specimen container must identify the patient uniquely. This may be text-based, numeric, bar-coded, etc. The form of this system is entirely at the discretion of each laboratory, so long as all primary collection containers and their aliquots have a unique label which one can audit back to full particulars of patient identification, collection date, specimen type, etc. Practical considerations of container size may limit the extent of such details. There must be an appropriate, consistently applied accessioning system.				
GEN.40900	2	**Specimen Date Received** The date (and time, if appropriate) that the specimen was received by the laboratory is recorded.					
GEN.40930	1	**Authorized Requestor** The laboratory have a mechanism to ensure that specimens are analyzed only at the request of an authorized person.	NOTE: The laboratory must perform tests only at the written or electronic request of an authorized person. In some U.S. States and other countries, individuals may order some laboratory tests without a physician's referral (direct-to-consumer testing).	✓*Written policy requiring test orders by authorized persons, if applicable in the jurisdiction in which the laboratory is located.*			
GEN.40932	2	**Verbal Test Authorization** For laboratories subject to U.S. regulations, the laboratory solicits written or electronic authorization for verbal orders within 30 days.	NOTE: The laboratory must retain the written authorization or record of efforts made to obtain a written authorization. In a managed office where the staff assistants are not employees of the physician/clinician, the staff should not sign a test requisition for the physician without some type of provider services agreement. This agreement must specify how the clinician has accepted responsibility for the tests ordered from the off-site laboratory. (This situation is different from the hospital environment, where the physician has personally signed the order sheet.)	✓*Records of follow-up to obtain written order*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL — HPO Path Volume II - Operations-Add-On and Verbal Test Requests (OPER001)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3900/policy_3900.pdf	
GEN.40935	2	**Test Order Read Back** The laboratory has a policy that personnel receiving verbal or phone orders read back the entire order to verify accuracy of transcription.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL — HPO Path Volume II - Operations-Add-On and Verbal Test Requests (OPER001)	http://www.insidehopkinsmedicine.org/hpo/policies/68/3900/policy_3900.pdf	
GEN.40938	1	**Unclear Test Order** The laboratory has a policy on confirmation of test orders that may be unclear (e.g. orders using non-standard or non-specific terms).					
GEN.40942	2	**Specimen Container Analytic Interference** The laboratory director or designee evaluates significant changes to specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed and approves them for use.	***NOTE: Si***gnificant changes include new container types, a different container type (eg. a plain container to one with an additive), and when changing to a different vendor. To ensure that the specimen containers do not contribute to analytic interference, the laboratory director or designee must review clinical literature, as available, and evaluate information from specimen collection container and instrument/method manufacturers. Based on the information reviewed and the test systems that will be impacted, the laboratory director or designee determines whether verification by the laboratory is indicated. Manufacturers of collection containers must perform studies to demonstrate safety and efficacy of the product prior to marketing their products. However, it is not feasible for manufacturers to evaluate all assays on all instrument and methods. The CLSI Guideline GP34-A, Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, recommends performing a comparative tube evaluation when changing to a different type of tube (e.g. gel, additive, different vendor). A sample protocol for end user evaluation is provided in the CLSI guideline. For some analytes it may be necessary to evaluate the effectiveness of the specimen collection containers to accurately maintain analyte stability over time.	✓*Records of specimen container evaluation for analytic interference with approval for use*			
		The following two requirements apply to laboratories that have a centralized specimen processing area					
GEN.41017	2	**Centrifuge Operating Speeds** The operating speeds of centrifuges checked at least annually as needed for the intended use, and this is done in a safe manner.	NOTE: For centrifuges with safety mechanism preventing the opening of the lid while in operation, the checks of rpm should be performed only by an authorized service representative of the manufacturer or an appropriately trained clinical engineer.	✓*Records of verification of operating speeds documented at least annually*			

GEN.41042	2	**Refrigerator/Freezer Temperatures** Refrigerator/freezer temperatures are checked and recorded daily using a calibrated thermometer.	NOTE: This checklist requirement applies to refrigerators/freezers containing reagents or patient/client specimens. "Daily" means every day (7 days per week, 52 weeks per year). The laboratory must define the acceptable temperature ranges for these units. If temperature(s) are found to be outside of the acceptable range, the laboratory must record appropriate corrective action, which may include evaluation of contents for adverse effects. Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually the identity of the individual recording the temperature(s) must be recorded((the initials of the individual are adequate). If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate the daily functionality of the system. If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (**eg**, laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.				
GEN.41042 cont.	2	**Refrigerator/Freezer Temperatures**	A frost-free freezer may be used to store reagents and controls provided that the function of these materials is not compromised. Storage conditions must remain within the specifications of the manufacturer of the reagent or control. Temperatures may be recorded using a continuous monitoring system or a maximum/minimum thermometer. Thermal containers within the freezer may be used. Patient samples may be stored in frost free freezers only if protected from thawing. The laboratory must retain records showing that the temperatures stay within the defined range.				
		RESULTS REPORTING AND REFERRAL OF TESTING ***The laboratory must provide useful clinical data. Data must be legible, accurate, reported in clearly designated units of measurement, and promptly reported to persons authorized by law to receive and use medical information.*** ***A referral laboratory is any outside location to which the referring laboratory submits specimens or material for testing [CLSI guideline QMS05-A2]. In the requirements that follow, the phrase "referral laboratory" means an independent, external enterprise. The phrase "off-site location" is used when part of the testing essential for a final result is performed at a closely affiliated or satellite laboratory. Off-site locations include offices where images or data files are reviewed and interpreted with frequency (i.e. recurrent or on a regular basis). The addition of an electronic signature to a final report is not off-site laboratory testing, nor is the rendering of a consultative opinion that does not involve a specimen submitted for testing.***					
GEN.41067	1	**Content/Format Report Review** An individual meeting CAP laboratory director qualifications reviews and approves the content and format of paper and electronic patient reports at least every two years.	NOTE: The laboratory director (or a designee who meets CAP qualifications for laboratory director) must review and, at least every two years, approve the content and format of laboratory patient reports (whether paper or computer screen images) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff. Further details on review of electronic reports are given in GEN.48500.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-— HPO Path Volume II:Quality Management System- Information Management Report Format review.	https://hpo.johnshopkins.edu/Hopkins/policies/68/3578/policy_3578.pdf?_=0.703773257806	
GEN.41077 R	1	**Reporting Outside Results** There is a policy for laboratory director (or designee meeting CAP director qualifications) input regarding whether outside laboratory results are reported through the primary reporting system (i.e. the laboratory information system or the institution's electronic medical record).	NOTE: At times patients may bring test results from outside laboratories to their physicians. Patients' physicians may request, or institutional policy may dictate, that such results (or other test results from outside laboratories) be integrated into the laboratory's primary reporting system (i.e. the LIS or the institution's electronic medical record). The laboratory director should be aware of whether results from outside laboratories are reported through the laboratory information system or the electronic medical record system. It is recognized that the laboratory director may not be in a position to prohibit entry of outside laboratory results into the electronic medical record system. However, if such results are integrated, there must be an indication available to the person viewing such results that the results originated from an outside laboratory. If the laboratory director believes that certain test results should not be integrated into the primary reporting system, one option is to include such results in a section of the electronic medical record other than the laboratory database.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-— HPO Path Volume II: Referral Laboratory Services (ADM004) II -B. Efficincy and Timeliness of Laboratory--4. Handling reports mailed or sent to the John Hopkins Department of Pathology.	http://www.insidehopkinsmedicine.org/hpo/policies/68/4243/policy_4243.pdf	
GEN.41096 R	2	**Report Elements** The paper or electronic report include the following elements: 1. Name and address of testing laboratory (see note below) 2. Patient name and identification number, or unique patient identifier and identification number 3. Name of physician of record, or legally authorized person ordering test, as appropriate 4. Date of specimen collection, and if appropriate, time of collection 5. Date of release of report (if not on the report, this information should be readily accessible) 6. Time of release of report, if applicable (if not on the report, this information should be readily accessible) 7. Specimen source, when applicable 8. Test result(s) (and units of measurement, when applicable) 9. Reference intervals, as applicable 10. Conditions of specimen that may limit adequacy of testing	NOTE: All of the above data elements, as applicable, must be available in the laboratory information system or in paper records, and must be in the report that is available/sent to the clinician, whether electronic or paper, including electronic reports in systems interfaced to the laboratory information system directly or through middleware or an interface engine. For electronic reports, data elements need not all be present on one screen, but must be readily available. The paper or electronic report must include the name and address of referral laboratories where patient testing was performed. For laboratories subject to US regulations, a "referral laboratory" includes outside referral laboratories as well as any affiliated or special function laboratory that is separately accredited and has a different CLIA registration number than the referring laboratory. For electronic reports, the name and address of referral laboratories need not all be present on the same screen(s) as the results but must be available to the clinician in the information system. Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable. Patient reports must state the name of the physician (or other legally authorized person) ordering the test(s) or a physician of record. In those institutions where there are multiple ordering physicians and/or frequent changing of attending physicians, the ordering physician should be easily identifiable through a computer audit trail or other records of the test order. Referral laboratories accredited by the CAP must providea copy of the results to the referring laboratory (Exceptions to this requirement may be made under special circumstances or for special categories of testing, such as drugs of abuse or employee drug testing. The laboratory director may make these exceptions.). Results may be reported to the ordering physician of record (or other legally authorized person) by either the referral laboratory or the referring laboratory.				LIS are responsible for ensuring that all reports include the required elements. **If the laboboratory does not have access to the LIS all paper reports must follow this requirement.**
GEN.41300	2	**Report Retention and Retrieval** Copies or files of reports are legible and retained by the laboratory in a manner that permits prompt retrieval of the information.	NOTE: The length of time that reported data are retained in the laboratory may vary; however, the reported results must be retained for that period encompassing a high frequency of requests for the data. In all circumstances, a hospital laboratory must have access to the patient's chart where the information is permanently retained.				
GEN.41303	2	**Patient Confidentiality** The laboratory ensures that internal and external storage and transfer of data maintains patient confidentiality and security.	NOTE: Written procedures must address patient confidentially during transfer of data to external referral laboratories or other service providers. This must include cloud based computing (e.g. for storage of confidential data), as appropriate The laboratory must audit compliance with the patient privacy procedures at least annually.	✓*Records of patient privacy audit for compliance with the Health Insurance Portability and Accountability Act (HIPAA)*	Request evidence of compliace from the HIPPA office	http://intranet.insidehopkinsmedicine.org/privacy_office/Security_transactions/security.html	see appedix -Johns Hopkins HIPAA Security Compliance Matrix – 2015
GEN.41304	2	**Patient Data Accessibility** ***There is a written policy*** to ensure that patient data are accessible ***in a timely manner*** only to those individuals who are authorized to review test results.	NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. ***For completed tests, these results must generally be provided no later than 30 days after such a request. Under the HIPAA Privacy Rule, only the patient or a personal representative, defined as an individual who has authority under applicable law to make health care decisions for the patient, can be given access to a patient's personal health data. Laboratories must take reasonable steps to verify the identity of the patient and the authority of a personal representative to have access to an individual's protected health information. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable. For additional information see Department of Health and Human Services. Medicare and Medicaid Services. "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule." Fed Reg 79:7290 (2014): 45CFR164.502(a); 45CFR164.524.***		Pathology Dept. : Resources - HIPPA Compliance Link Use of MyCHART	http://www.insidehopkinsmedicine.org/hipaa/	
GEN.41306	2	**Analyst Tracking ID** There is a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established.	NOTE: If results are released using autoverification, the system must be capable of identifying those test results that have been autoverified. In addition, the laboratory should be able to identify the technologist responsible for the instrument producing the result, such as through daily bench assignment charts, instrument set-up logs, or electronic audit trail.				

GEN.41307	2	**Report Errors** When errors are detected in patient test reports, the laboratory promptly notify responsible clinical personnel or referring laboratory as applicable and issue a corrected report.	NOTE: Notification should include the department of health or other legal entity as required by local regulations.	*✓Records of report error notification and corrected report*			
GEN.41310	2	***Corrected* Report** All corrected reports of previously reported, incorrect patient results are, identified as corrected, and both the corrected and original data are clearly identified as such.	NOTE: 1.As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the corrected information. The previous information and the corrected information must be identified as such, and the original data must be present in the corrected report (for paper reports), or linked electronically or logically to the corrected information (in electronic reports). 2. This requirement applies to electronic reports in the laboratory information system, and to the data systems interfaced to the laboratory information system either directly or through middleware or an interface engine (but not to systems that are further downstream in the interface chain). 3. Displays in an electronic medical record (EMR) downstream from the laboratory should include the original report as well as the corrected report. The report elements listed in GEN.41096 should be included in the EMR. 4. The correction should add explanatory language if an explanation would be helpful to the user. For example, a comment about transport or sample storage conditions uncovered post-analysis can help frame an original, invalid result. 5. For changes to anatomic pathology and cytopathology reports, refer to ANP.12185 and CYP.06475.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Customer focus-— HPO Path Volume II-PROCEDURE FOR CORRECTION OF PATIENT RECORDS	https://hpo.johnshopkins.edu/Topkins/policies/68/4471/policy_4471.pdf?_=0.9760978947023	
GEN.41312	2	**Multiple *corrections*** When there are multiple sequential corrections of a single test result, are all corrections referenced in sequential order on subsequent reports.	NOTE: When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the 'true' result. All corrections should be referenced in the patient report.				
GEN.41316	2	**Infectious Disease Reporting** There is a policy regarding the timely communication, and documentation thereof, of diagnoses of infectious diseases of particular significance (e.g., human immunodeficiency virus, ***and*** tuberculosis).	NOTE: The laboratory should have a policy to ensure that diagnoses of human immunodeficiency virus infection, and other serious infections (for example, tuberculosis) are communicated to the responsible clinician in a timely manner. The intent of this checklist item is NOT to require that these diagnoses be treated as critical results (this decision is up to the laboratory director); rather, the intent is that the laboratory ***assures*** that its reporting system is effective.				
GEN.41325	2	**Newborn Screening Results** There must be a procedure for handling invalid and positive newborn screening results for samples submitted to other laboratories for testing.	NOTE: This requirement applies to the testing of whole blood heel stick samples from the newborn after birth on filter paper collection devices for the routine screening of congenital disorders. Positive results include those results that are outside of the expected range of testing results established for a particular condition. Invalid results include situations where the laboratory is unable to complete the screening process due to an unsuitable specimen, test, or incomplete information. Due to the urgent nature of newborn screening test results, procedures must include a process to track requests for repeat testing so that repeat specimens are submitted within the follow-up/recollection timeframe specified by the testing laboratory.				
GEN.41345	2	**Turnaround Time** The laboratory defined turnaround times (ie., the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and it has a policy for notifying the requester when testing is delayed.	NOTE: This does NOT imply that all instances of delayed reporting for all tests must lead to formal notification of clinical personnel. Rather, clinicians and laboratories must have a jointly agreed upon policy for when such notification is important for patient care.	*✓Written policy defining test reporting turnaround time and process for communication of delays in turnaround time*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Quality Management -— HPO /Quality Management System. Section IX-Customer Service- Delay in reporting	http://www.insidehopkinsmedicine.org/hpo/policies/68/3578/policy_3578.pdf	Each Laboratory should set written criteria for TAT and notification of delay to requestor
GEN.41350 R	2	***Referral* Laboratory Selection** The laboratory has a written procedure for the selection and evaluation of laboratories to which it refers specimens or materials for testing.	NOTE: ***1***. The laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for selecting referral laboratories. ***2***. Selection of referral laboratories must be based primarily upon the quality of performance of such laboratories. ***3***. "Specimens" or materials for testing include intermediate processing such as histologic and cytologic processing, preliminary analysis such as flow cytometry, and the use of distributive testing in next-generation sequencing. It also includes the referral of images or data files to an off-site location for interpretation. ***4***. For laboratories subject to U.S. regulations: for tests in disciplines covered by CLIA, specimens and materials for testingmust be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements (or more stringent) as determined by the CAP and/or the CMS, this includes off-site locations where images or data files are frequently referred for review and interpretation. Laboratories that are part of the Department of Defense* must meet the referral policies of the Clinical Laboratory Improvement Program (CLIP). * With respect to patients on research protocols, whose tests are referred to a research laboratory: if those test results are used for patient management decisions, the research laboratory must be CLIA-certified, or meet equivalent requirements as determined by CMS. ***5***. For disciplines not covered by CLIA (**eg**., histology, ***embryology***), laboratories subject to U.S. regulations must refer specimens to a laboratory accredited by CAP or a CAP-accepted organization.* ***6***. For non-U.S. laboratories, whenever possible, specimens and materials for testing should be referred to a laboratory accredited by CAP, accredited to an established international standard from a recognized organization; or certified by an appropriate government agency. The inspector may need to exercise judgment with respect to determining if a referral laboratory is acceptable.	*✓Records of the monitoring of reference laboratory services (e.g. problem log, review of reports)*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-— HPO Path Volume II: Referral Laboratory Services (ADM004) II	http://www.insidehopkinsmedicine.org/hpo/policies/68/4243/policy_4243.pdf	Contact the CQI office if you have any question regarding reference laboratories
GEN.41350 cont	2	***Referral* Laboratory Selection** The laboratory has a written procedure for the selection and evaluation of laboratories to which it refers specimens or materials for testing	7. It is the responsibility of the laboratory director or designee to monitor the turnaround time and quality of test results received from referral laboratories ** Yor overseas US military laboratories only, an exception to this requirement is acceptable if both of the following conditions are met: 1. Rapid turnaround time (TAT) is required to prevent either a delay in patient treatment/diagnosis or specimen degradation, and an acceptable TAT cannot be provided by a CAP-accredited or CLIA-certified laboratory. 2. The laboratory director has determined that the alternative testing site meets requirements that are equivalent to those of a CLIP or CLIA-certified laboratory as stipulated in the CLIP/CLIA Manual (11-32(B)(c). This assessment must be recorded.				
GEN.41360	2	**Selection and Evaluation of Services - <u>Biorepositories</u> Only.** 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, eg, 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.	*✓Records of evaluation or qualification (eg, certification, publications, audits or biorepository director-approved records of acceptable quality)*			
GEN.41430	2	**Referral Laboratory Report Retention** For samples referred to another laboratory, the original or an exact copy of the testing laboratory's report retained by the referring laboratory.	NOTE: The report may be retained on paper or in electronic format. Exceptions to this requirement may be made under special circumstances or for special categories, such as drugs of abuse or employee drug testing. The laboratory director may make these exceptions.	*✓Retained original referral laboratory reports OR direct access to referral laboratory reports via electronic transmission from the referral laboratory*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-— HPO Path Volume II: Referral Laboratory Services (ADM004) II	http://www.insidehopkinsmedicine.org/hpo/policies/68/4243/policy_4243.pdf	
GEN.41440	2	**Referral Laboratory Results Reporting** The essential elements of referred test results reported by the referring laboratory as received from the referral laboratory, without alterations that could affect clinical interpretation.	NOTE: If the laboratory transcribes results from the referral laboratory report, the test result(s), interpretation, and information directly related to the interpretation must be copied exactly as reported by the referral laboratory. This does not mandate that the referring laboratory report every word nor retain the exact format of the referral laboratory report. There is no requirement to fully replicate the complete content of the referral laboratory report beyond the results and interpretation. Suggestions for follow-up testing may, for example, be omitted at the discretion of the laboratory director.	*✓Patient results from the reference laboratory consistent with laboratory-issued patient reports*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-— HPO Path Volume II: Referral Laboratory Services (ADM004)	http://www.insidehopkinsmedicine.org/hpo/policies/68/4243/policy_4243.pdf	
			QUALITY OF WATER AND GLASSWARE WASHING				

GEN.41500	2	**Defined Water Types** The laboratory defines the specific type of water required for each of its testing procedures and water quality is tested at least annually.	NOTE: The laboratory should define the type of water necessary for each of its procedures, and should have an adequate supply of same. The current edition of CLSI Guideline GP4D-A4 AMD defines the following grades of water: Clinical Laboratory Reagent Water (CLRW), suitable for most laboratory procedures; Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications than CLRW; Instrument Feed Water, specified by IVD manufacturers as suitable for use with their measurement systems; and Commercially Bottled Purified Water that may be suitable for certain laboratory procedures. CLRW is not required if the laboratory is able to ***record*** reliable results with an alternate grade of water. The following specification for CLRW is adapted from this guideline and should be met at time of in-house production: Bacteria may inactivate reagents, contribute to total organic contamination, or alter optical properties of test solutions. Resistivity provides a nonspecific measure of the ion content. Particulate matter includes organic carbon from biofilms and inorganic aggregates that can vary over time, both in nature of the contamination and the effect on the laboratory use. The CLSI Guideline provides testing information for microbial content, and resistivity, as well as total organic carbon; earlier specifications for silicates have been removed. It gives instructions for the preparation of the various types of water. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water. The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and ***recorded*** at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be ***recorded*** if	✓*Procedures for water quality testing AND* ✓*Records of water quality testing AND* ✓***Record** of corrective action when water quality does not meet specifications*			
GEN.41500 cont.	2	**Defined Water Types**	water does not meet acceptability criteria. For CLRW, minimum monitoring includes resistivity and microbiology cultures. Other monitoring criteria, such as pH, endotoxin/pyrogens, silicates and organic contaminants are at the discretion of the laboratory. Testing for these substances must be recorded only if the laboratory finds that they adversely affect specific test methods. The laboratory must determine the level of testing necessary for other grades of water in use. Typically, "sterile (pharmaceutical) water" is not manufactured to meet the specifications of CLRW, and should not be used as its equivalent.For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water. **For CLRW content:** **maximum microbial contente CFU/ml = 10; minimum resistivity megHm-cm = 10 (in line); particulate matter = 0.22 um filter**	✓*Procedures for water quality testing AND* ✓*Records of water quality testing AND* ✓***Record** of corrective action when water quality does not meet specifications*			
GEN.41770	2	**Glassware Cleaning** There are **written** procedures for handling and cleaning glassware, including methods for testing for detergent removal and actions to be taken if detergent residue is detected.	NOTE: Special instructions for micropipettes, cuvets, acid washing, etc. must be included. A simple procedure to check for detergent residue uses bromcresol purple (0.1 g bromcresol purple in 50 mL ethyl alcohol). Pipette a column of 5 cm distilled water into a representative, washed, glassware item. Add two drops bromcresol solution. A purple color reveals residual detergent. A yellow color indicates satisfactory rinsing.	✓*Records of detergent residue testing*			If glassware washing is performed in Laboratory a documented procedure must be available, to include how residue check is performed, and records of residue testing
		LABORATORY COMPUTER SERVICES					
		Multiple types of laboratory information systems (LIS) exist. Traditional systems have a local "host" database (ie, the computer hardware and software) serving the information needs of the laboratory; the laboratory is the only "user." In the current environment, the host is often physically remote from the laboratory and in fact the host may have multiple user laboratories. Many of the Computer Services requirements may apply to host, user, or both, depending on how information services are organized in the laboratory. The laboratory is responsible for ensuring that the provider of host functions meets CAP requirements (seeGEN.42195, below). ***The requirements in this section do NOT apply to the following:*** ***1. Desktop calculators*** ***2. Small programmable technical computers*** ***3. Purchased services such as the Quality Assurance Service or Laboratory Management Index Service of the College of American Pathologists*** ***4. Micro computers used solely for word processing, spreadsheets, or similar single user functions*** ***5. Dedicated microprocessors or workstations that are an integral part of an analytic instrument***				
GEN.42195 R	2	**Remote LIS** If components of the LIS are located at a facility other than the one under this CAP accreditation number, there is evidence that the remote facility complies with CAP requirements for host LIS functions	NOTE: This requirement does not apply if all components of the LIS are under the laboratory's CAP/CLIA-88 registration number. This requirement may be addressed by a copy of the CAP accreditation certificate from other sites, or evidence that the computer facility has been provided a copy of this Checklist, and has satisfactorily addressed the contents of the Computer Facility section, and all other pertinent requirements, ***In addition, all laboratories must have records showing compliance with the following site-specific LIS requirements:*** ***• GEN.43055 (Computer System Training)*** ***• GEN.43056 (Computer Malfunction Nodification)*** ***• GEN.42150 (User Authentication)*** ***• GEN.43450 (Calculated Patient Data Verification)*** ***• GEN.43817 (Downtime Result Reporting)*** ***• GEN.43875 (Autoverification Validation)*** ***• GEN.43893 (Autoverification Suspension)*** ***• GEN.48500 (Interface Result Integrity)*** ***These records may include studies and activities performed by the laboratory and/or by the host LIS site on behalf of the laboratory.***				
		COMPUTER FACILITY					
GEN.42750	1	**Computer Facility Maintenance** The computer facility and equipment are clean, well-maintained and adequately ventilated with appropriate environmental control.	NOTE: The computer facilities should be clean, well maintained, and in a location that is environmentally controlled, as required by the most restrictive vendor specifications.				Surveyors will be referred to LIS
GEN.42800	2	**LIS Fire Equipment** fire-fighting equipment (extinguishers) is appropriate for electrical components available.	NOTE: Acceptable fire-fighting equipment/extinguishers in areas with information technology equipment may include: 1. Automatic sprinkler systems that are valved separately from other systems 2. Gaseous clean agent extinguishers systems 3. Listed portable fire extinguishers of carbon dioxide or halogenated agent type 4. Listed extinguishers with a minimum rating of 2-A for ordinary combustible material (paper and/or plastics) 5. Gaseous agent inside units or total flooding systems when there is critical need, e.g. to protect data in process, reduce equipment damage and to facilitate a return to service Dry chemical extinguishers are not recommended because of the corrosive damage they cause. In the instance where no other extinguisher is available and there is imminent danger to personnel or property however, a dry extinguisher may be used.				Surveyors will be referred to LIS
GEN.42900	2	**LIS Power** The computer system is adequately protected against electrical power interruptions and surges.	NOTE: Protection from electrical surges and interruptions must be adequate to prevent loss of data. An uninterruptible power system (UPS) or similar protective device (e.g., isolation transformer) must be considered. Periodic testing of this protective equipment to ensure protection of data and proper shutdown of computer equipment is considered best practice.				Surveyors will be referred to LIS
			HARDWARE AND SOFTWARE				
GEN.43022R	2	**LIS Testing** There are records that programs are adequately tested for proper functioning when first installed and after any modifications, and that the laboratory director or designee has approved the use of all new programs and modifications.	NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications, including assessment after implementation in the live (production) system. Any changes or modifications to the system must be recorded, and the laboratory director or designee must approve all changes, additions and deletions in programs, the test library, and major computer functions before they are released. This applies both to locally installed and remotely hosted software. Records must be retained for at least two years beyond the service life of the system.				Surveyors will be referred to LIS
GEN.43033	1	**Custom LIS** Customized software, and modifications to that software, are appropriately documented and records allow for tracking to identify persons that have added or modified that software.	NOTE: The purpose of the computer program, the way it functions, and its interaction with other programs must be clearly stated. The level of detail should be adequate to support trouble-shooting, system modifications, or additional programming.				Surveyors will be referred to LIS
GEN.43035	2	**Software Issue Tracking and Resolution - <u>Biorepositories Only</u>** There is an adequate tracking system with usage policies to identify and report all malfunctions or issues with biorepository software, and to track and record their resolution.	NOTE: The tracking system should also include time-stamped reports of problems, responses to reports, steps taken to resolve issues, and final resolution of issues.				
GEN.43037	2	**Software Change Control - <u>Biorepositories Only</u>** There is a written procedure for recording all software changes, including those associated with problem resolution and planned upgrades. Software changes are linked with issues in the biorepository software issue tracking system, as appropriate.	NOTE: The record of changes may be completely derived from the software issue tracking system if routine changes, such as planned upgrades, are included in it.				

GEN.43040	2	**LIS Policy and Procedure Approval** The laboratory director or designee reviews and approves all new LIS policies and procedures, as well as substantial changes to existing documents before implementation.	NOTE: Procedures should be appropriate to the level of use of the system, and must encompass the day-to-day activities of the laboratory staff as well as the daily operations of the Information Technology staff.				
GEN.43055	2	**Computer System Training** There **are records for training of** all users of the computer system initially, after system modification, and after installation of a new system.	NOTE: Review of LIS policies and procedures relevant to the scope of duties must be incorporated into the training				
GEN.43066	2	**Computer Malfunction Notification** There is a written **procedure** with instructions for contacting a responsible person (e.g., Computer System Manager) in case of computer malfunction.					Surveyors will be referred to LIS
			SYSTEM SECURITY				
GEN.43150	2	**User Authentication** There are explicit written policies that specify who may access the computer system, how the access is obtained, and how the security of access is maintained (e.g. inactivated when personnel leave, not posted on terminals).	NOTE: The laboratory should establish security (user) codes to permit only specifically authorized individuals to access patient / client data, or alter programs. Examples of best practices include: periodic alteration of passwords by users; minimum character length for passwords; password complexity requirements (e.g. a combination of alphanumeric characters); recording of failed log-on attempts with user lock-out after a defined number of unsuccessful log-on attempts. Access control policies should include physical entry to data center(s) housing the LIS, logging into server(s) operating system hosting the LIS, as well as software system(s) that comprise the LIS.				Surveyors will be referred to LIS
GEN.43200	2	**User Authorization Privileges** User Authorization Privileges accessprivileges in place to confine the level of access of authenticated users to those functions they are authorized to use, to fulfill their job responsibilities.	NOTE: The laboratory should establish codesuser roles and/or policies that define those who may only access patient/client data and users who are authorized to enter results, change results, or alter computer tables or programs. Personnel user rights should be limited to only the level needed to execute assigned responsibilities, also referred to as the "minimum necessary." If data in other computer systems can be accessed through the LIS (e.g. pharmacy or medical records), policies must prevent unauthorized access to the data through the LIS to permit only specifically authorized individuals to access patient/client data or alter programs.				Surveyors will be referred to LIS
GEN.43262	1	**Unauthorized Software Installation** **There are written policies** and procedures that govern installation of software on any computer used by the laboratory.	NOTE: Laboratory computers often serve multiple functions. Many of these computers are connected in a network. The security of the system should be sufficient to prevent the casual user from installing software. Such unauthorized installation may cause instability of the operating system or introduce other unwanted consequences. Many operating systems allow procedures to restrict certain users from installing software.				Surveyors will be referred to LIS
GEN.43325	2	**Public Network Security** If the facility uses a public network, such as the Internet, as a data exchange medium, there are network security measures in place to ensure confidentiality of patient data.	NOTE: Patient information sent over a public domain such as the Internet **or stored in "the cloud,"** is considered "potentially public". Thus it may be accessible to some unauthorized parties on that network. Systems must be in place to protect network traffic, such as 'fire walls' and data encryption schemes. If such storage is used for patient information, encryption at rest and encryption in transit should be implemented to ensure network and data security.	✓*Written policy defining mechanism for data protection*			Surveyors will be referred to LIS
GEN.43335	1	System Vulnerability Testing - **Bizrepositories Only** Systems are systematically tested for access, privilege escalation, and other vulnerabilities that could lead to inadvertent or unauthorized disclosure and modification of data.		✓*Records and results of vulnerability tests AND* ✓*Records of corrective action if a vulnerability is identified*			
			PATIENT / CLIENT DATA				
GEN.43450	2	**Calculated Patient Data Verification** Calculated values that reported with patient results are reviewed every two years, or when a system change is made that may affect the calculations.	NOTE: This checklist requirement applies only to calculations based on formulas modifiable by the user. Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked to ensure accuracy and records retained. This requirement applies to laboratory information systems, middleware, and analyzers. More frequent checks may be required for certain specific calculations, as delineated elsewhere in the checklists (e.g. INR). When calculations are performed by an LIS shared by multiple laboratories, this review only needs to be done at one location and each individual laboratory must have access to copy of the review records.. However, any calculations specific to an individual laboratory's methodology must be reviewed by that laboratory and the record of that review must be available.	✓*Records of validation of calculated test results*			
GEN.43750	2	**Specimen Quality Comment** The system provides for comments on specimen quality that might compromise the accuracy of analytic results (e.g., hemolyzed, lipemic).		✓*Patient reports*			Surveyors will be referred to LIS
GEN.43800	2	**Data Input ID** There is an adequate system to identify all individuals who have entered and/or modified patient / client data or control files.	NOTE: When individual tests from a single test order (e.g., multiple tests with same accession number) are performed by separate individuals and the test result is entered into the LIS, the system must provide an audit trail to record each person involved. For example, a single accession number having orders for electrolytes and a lipid panel may have testing done by two or more individuals. The laboratory should be able to identify the responsible personnel who performed each test and posted the data. This includes sequential corrections made to a single test result. If autoverification is used, then the audit trail should reflect that the result was verified automatically at a given time. With point-of-care testing, if the individual performing the test is different than the individual entering test data into the LIS, both should be uniquely identified by the system and retrievable by audit trail.				Surveyors will be referred to LIS
GEN.43825	2	**Result Verification** Are manual and automated result entries verified before final acceptance and reporting by the computer.	NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is checking the result against the reportable range and critical results for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail. * This checklist question does not apply to autoverification procedures (see below).				
GEN.43837	2	**Downtime Result Reporting** There are written procedures to ensure reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system.					Laboratories must have procedures available for computer down time
			AUTOVERIFICATION				
		Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, ***and/or middleware,*** *where they are compared against laboratory-defined acceptance parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats* ***as a laboratory-verified result*** *without any additional laboratory staff intervention. Any data that fall outside the defined parameters are reviewed by laboratory staff prior to reporting.* ***Autoverification should be distinguished from autofiling, where results are released by laboratory staff or instrument operators and automatically filed without any rules-based evaluation.***					
GEN.43875 R	2	**Autoverification Validation** The laboratory has records that the autoverification process was validated initially, and whenever there is a change to the system that could affect the autoverification logic.	NOTE: The range of results for which autoverification is acceptable must be defined for all patient tests subject to autoverification. Validation of autoverification must include a process to confirm that the autoverification algorithm decision rules are functioning properly, including the use of previously assayed specimens with results that challenge the algorithm. Examples of specimens that may be needed to validate the autoverification algorithm decision rules may include specimens with analyte concentrations within the normal reference limit, above or below the reference limits, above or below the analytic measurement range, and in the critical range. Specimens with known interferences and specimens that require calculations should also be used, when applicable. When changes are made that might affect the autoverification decision algorithm, validation appropriate to the scope and nature of the change must be performed.	✓*Records of autoverification validation studies, approval AND* ✓*Records of ongoing retesting of the autoverification process at least annually and at changes to the system*			
GEN.43878	2	**Autoverification QC Samples** For all test results subject to autoverification, the laboratory ensures that applicable quality control samples have been run within an appropriate time period, with acceptable results.	NOTE: This requirement may be met by, 1) the computer system automatically checking quality control status prior to autoverification, or, 2) manually disabling autoverification after any unacceptable QC result, or when QC has not been run within the required time interval.	✓*Procedure defining the QC process AND* ✓*QC data to show that QC was performed at defined intervals*			
GEN.43881	2	**Autoverification Results** Results are compared with an appropriate range of acceptable values **and flags or warnings reviewed** prior to autoverification.	NOTE: Appropriate comparisons include checking patient results against absurd and critical results requiring manual intervention (repeat testing, dilution, telephone notification of results, etc.) The mere presence of a flag may not disqualify a result from autoverification, but any flag that is not specifically recognized by the autoverification program must cause the flagged result to be held for manual review.	✓*Records of system rules including comparison of patient results against absurd and critical values.*			

GEN.43887	1	**Autoverification Audit Trail** The audit trail in the computer system identify all test results that were autoverified, and the date/time of autoverification.					
GEN.43890	1	**Autoverification Delta Checks** The autoverification process includes all delta checks that the laboratory performs prior to manual release of test results.	NOTE: This requirement does not require delta-checking for all autoverified results, but the laboratory's delta-checking procedures should be the same for manually released and autoverified test results.	*✓Records of system rules including the use of delta checks when appropriate*			
GEN.43893	2	**Autoverification Suspension** The laboratory have a procedure for rapid suspension of autoverification.	NOTE: Laboratory personnel should be able to suspend autoverification in the event of a problem with a test method, analytic instrument, or the autoverification program.				
			DATA RETRIEVAL AND PRESERVATION				
GEN.43900	2	**Archived Test Result** A complete copy of archived patient test results can be retrieved, including original reference intervals and interpretive comments, including any flags or footnotes that were present in the original report, and the date of the original report.	NOTE: Stored patient result data and archival information must be easily and readily retrievable within a time frame consistent with patient care needs.				
GEN.43910 N	2	**Archived Data - Biorepositories Only** Access to archived data, including all data relevant to the biospecimens through the original reports is readily available.	NOTE: Stored data and archival information must be easily and readily retrievable within a time frame consistent with research needs.				
GEN.43920	1	**Multiple Analyzer ID** When multiple identical analyzers are used, they are uniquely identified such that a test result may be appropriately traced back to the instrument performing the test.	NOTE: Best practice is to store these data in the LIS.				
GEN.43946	2	**Data Preservation/Destructive Event** There are written procedures for the preservation of data and equipment in case of an unexpected destructive event (eg, fire, flood, ***malicious incident***) , software failure and/or hardware failure, and these procedures allow for the timely restoration of service, including data integrity check	NOTE: Procedures must 1) be adequate to address scheduled and unscheduled interruptions of power or function; 2) be tested periodically for effectiveness; and 3) include systems to backup programs and data; These procedures can include , but are not limited to, 1) steps to limit the extent of the destructive event, 2) periodic backing up and storing of information, 3) off-site storage of backup data,4) restoring information from backed up media. The procedures should specifically address the recoverability of patient / Client information. Changes to hardware and software commonly require review and reevaluation of these written procedures. These procedures must specifically address the physical environment and equipment. and are often addressed by the organization's disaster plan.				Surveyors will be referred to SOFT
			INTERPHASES				
GEN.46000	1	**Reference Intervals /Units Transmission** As applicable, reference intervals and units of measure for every test are transmitted with thepatient result across the interface.	NOTE: The reference interval , including units of measure, may be specific for a given patient result, and should be attached to that result such that it will be displayed along with the patient result.				Surveyors will be referred to PDS
GEN.48500 R	2	**Interface Result Integrity** There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).	NOTE: Verification must be performed: ● Prior to implementation of an interface (i.e., pre go-live), and ● Whenever any change is made to an existing interface that could affect the accuracy of transmission of patient results. Verification of accurate data transmission from the LIS to other systems must be performed by reviewing data in the first downstream interfaced system in which the ordering clinician / client (e.g. referring laboratory) may be expected to routinely access patient data. If the LIS has separate interfaces to multiple receiving systems in which patient data can be accessed by clinicians, then reports from each receiving system must be validated. However, where multiple sites use the same recipient system (e.g. the same installed instance of an electronic medical record system), validation need only occur for the interface (i.e. at one of the sites) and not for each individual site that is served by that single installed system. Interface validation should include examples of individual results, test packages or batteries, abnormal flags, and results with reference intervals and comments/footnotes. Initial interface validation should include verification that corrected results for clinical laboratory and anatomic pathology results are handled accurately in the receiving system.	*✓Printed screen shots or other verification records*	(EPIC) Electronic Patient Record Laboratory Result Review	http://www.insidehoskinsmedicine.org/wp/policies/EB/4569/policy_4569.pdf	
GEN.48750	2	**LIS Interface Shutdown/Recovery** there are procedures for changes in laboratory functions necessary during partial or complete shutdown and recovery of systems that interface with the laboratory information system.	NOTE: These procedures must ensure integrity of patient test data. Procedures must include verifying recovery of interfaced systems, and replacement or updating of data files, as necessary.				Surveyors will be referred to LIS
			TELEPATHOLOGY AND REMOTE DATA ASSESSMENT				
		This section applies to telepathology in which digitized or analog video still image(s),or other data files (e.g. flow cytometry files, Sanger sequencing data) are examined and an interpretation is rendered at an off-site or remote location and that interpretation is included in a formal diagnostic report or in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is recorded in the patient record. This section may be applied to, but is not limited to the disciplines of anatomic pathology, cytopathology, hematopathology, cytogenetics, flow cytometry, histocompatibility, and molecular pathology. ***Requirements for remote data assessment do not apply to testing performed within the laboratory using the laboratory's validated software*** ***Telepathology modes include:*** ***■ Static telepathology – interpretation based on pre-selected still image(s)*** ***■ Dynamic telepathology - viewing real-time images (includes robotic microscopy, video streaming, and desktop sharing)*** ***■ Virtual slides/whole slide imaging*** ***This checklist section applies to:*** ***■ Primary diagnoses made by telepathology*** ***■ Frozen section diagnoses*** ***■ Formal second-opinion consultations*** ***■ Ancillary techniques in which the pathologist participates in interpretation of images*** ***■ Real-time evaluation of FNA specimens for triaging and preliminary diagnosis*** ***■ ■ ■ ■*** ***This checklist section is NOT applicable to:*** ***■ Informal reviews without formal reporting*** ***■ Educational or research use of these systems***				
GEN.50057	2	**Slide/Data File Patient Identification** There is a method for the individual reviewing cases for the telepathologist to ensure correct patient identificationfor slides/images and data file submitted for review.	NOTE: There are multiple ways to accomplish positive patient identification, including verbal communications, images of slide identifier, etc.	*✓Written procedure defining mechanism to positively identify slides/images*			Surveyors will be referred to LIS
GEN.50614	1	**Clinical Information Access** The individual reviewing cases has access to pertinent clinical information at the time of slide/image(s) or remote data file review.	NOTE: Typically this information includes at least the information on the requisition form.				Surveyors will be referred to LIS
GEN.50630	1	**Telepathology System Validation** The laboratory validates telepathology systems used for clinical diagnostic purposes by performing its own validation studies, including approval for use by the laboratory director (or designee who meets CAP director qualifications) before the technology is used for the intended diagnostic purpose(s).	NOTE: The specific components of the validation study are left to the discretion of the laboratory. As general guiding principles, the validation process should: ● Closely emulate the real-world clinical environment and involve specimen preparation types and clinical settings relevant to the intended use(s). ● Be carried out by a pathologist(s) adequately trained to use the system. Refer to GEN.52920 for requirements on validation of whole slide imaging	*✓Records of completed validation study with review and approval*			
GEN.51728	1	**Telepathology Training** The lab has a procedure addressing training requirements for all users of the telepathology system	NOTE: The training procedure should be role-specific, as defined in the approved laboratory procedures. Retraining may be required when significant system changes are made.	*✓Records for telepathology training in personnel files*			Surveyors will be referred to LIS
GEN.52842	2	**Patient Confidentiality - Telepathology and Remote Data Assessment** There are procedures in place to ensure that sites engaging in telepathology and remote data assessment provide reasonable confidentiality and security.	NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions. These security considerations must be particularly adhered to when using mobile devices in public places. For laboratories subject to US regulations, the procedures must be in conformance with HIPAA requirements.				Surveyors will be referred to LIS

GEN.52850	1	**Telepathology Result Records** The telepathology records include diagnoses made and statements of adequacy assessment, preliminary diagnosis, or recommendations for additional studies provided at the time of evaluation.					
GEN.52860	1	**Quality Management Program** Telepathology services are included in the laboratory's quality management program.	NOTE: For example, the laboratory might monitor the frequency of deferral cases, comparison to on-site evaluation, or consultation using traditional glass slide microscopy.				
			WHOLE SLIDE IMAGING				
		This section applies to laboratories using whole slide imaging systems for diagnostic purposes only (primary and/or consultation). ***This section is NOT applicable to:*** ***• Informal reviews without formal reporting*** ***• Educational or research use of these systems***					
GEN.52900	1	***Whole Slide Imaging User Training*** There are records showing that all users of the whole slide imaging system have been trained.	**NOTE**: Users of the whole slide imaging system include individuals responsible for slide scanning and digital slide quality assesment, as well as pathologists. The training procedure should include role-specific training, as defined in the approved laboratory procedures. Retraining may be required when significant system changes are made.	*✓Records for whole slide image training in personnel files*			
GEN.52920	1	***Whole Slide Imaging System Validation/Verification*** The laboratory validates or ***verifies*** whole slide imaging systems used for clinical diagnostic purposes by performing its own studies, including approval for use by the laboratory director (or designee who meets CAP director qualifications) before the technology is used for the intended diagnostic purpose(s).	***NOTE:*** The specific components of validation study ***or verification studies*** are left to the discretion of the laboratory. ***The approval or clearance of whole slide imaging systems by the FDA does not obviate the need for individual laboratories to verify the performance of these systems for the specific intended diagnostic purposes.*** As general guiding principles, the validation ***or verification*** process should: • Closely emulate the real-world clinical environment and involve specimen preparation types and clinical settings relevant to the intended use(s); • Be carried out by a pathologist(s) adequately trained to use the system; • Assess intraobserver concordance between digital and glass slides; • Encompass the entire whole slide imaging system, with reevaluation if a significant change is made to a previously validated ***or verified*** system.	*✓Records of completed validation or verification study with review and approval*			
			PERSONNEL				
		The laboratory must have personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files must contain records of educational qualifications, (e.g. copies of diplomas/transcripts, primary source verification reports), laboratory personnel licenses(where required), training and continuing education for each employee. Ideally, these files should be located in the laboratory, if they are retained outside of the laboratory they must be readily available to the inspector on the day of inspection. The inspector reviews the personnel files using the Laboratory Personnel Evaluation Roster. ***Biorepositories use the Biorepository Personnel Roster. There are additional personnel requirements that are applicable only to biorepository personnel in the Biorepository Personnel section.***				
			SECTION DIRECTORS/ (TECHNICAL SUPERVISOR)/ GENERAL SUPERVISORS				
		This section applies to laboratories performing high complexity test. The individuals fulfilling these roles must be identified on the CAP's Laboratory Personnel Evaluation Roster. ***The term "section director" may be considered synonymous to the technical supervisor in the checklist requirements . The term "supervisor" may be considered synonymous to the general supervisor in the checklist requirements. Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may serve as the section director and general supervisor, and may set position requirements more stringent than defined in the checklist.***					
GEN.53400	2	**Section Director (Technical Supervisor) Qualifications/Responsibilities** Section Directors/Technical Supervisors of high complexity testing meet defined qualifications for the specialties supervised and fulfill the expected responsibilities.	NOTE: The section director For high complexity testing, one or more individuals qualified as alechnical supervisor must be identified on the CAP's Laboratory Personnel Evaluation Roster. Requirements for the section directors of clinical cytogenetics, histocompatibility, ***molecular pathology,*** and transfusion medicine services are more stringent and are found in the Cytogenetics, Histocompatibility , ***Molecular Pathology,*** and Transfusion Medicine Checklists, respectively. The technical supervisor must meet the following requirements: **1.** MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with certification in anatomic pathology or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications equivalent to those required for certification. * If responsible for anatomic pathology or cytopathology must be board certified in anatomic pathology or possess equivalent qualifications. * If responsible for clinical pathology must be board certified in clinical pathology or possess equivalent qualifications. * If responsible for anatomic pathology and/or cytopathology, and clinical pathology, must be board certified in both anatomic and clinical pathology or possess equivalent qualifications OR **2.** For specialties other than Anatomic Pathology and Cytopathology, an individual will meet the qualifications of a technical supervisor providing the following qualifications are met: * MD or DO licensed to practice (if required) in the jurisdiction where the laboratory is located with at least one year of training and/or experience in high-complexity testing*; or * Doctoral degree in chemical, physical, biological or clinical laboratory science from an accredited institution with at least one year of laboratory training and/or experience in high complexity testing*; or * Master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution with at least two years of laboratory training and/or experience in high complexity testing*; or	*✓Records of qualifications including degree, transcript, equivalency evaluation, or current license (if required) AND* *✓Certification/registration (if required) and work history in related field AND* *✓Description of current duties and responsibilities AND* *✓Record of delegation of duties*	CLIA Resources ; CLIA Interpretive Guidelines - Refer to HR Department for Pathology - Non Pathology areas must have documentation available.	https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	CAP Personnel Requirement by Testing Complexity
GEN.53400 cont.R	2	**Section Director (Technical Supervisor) Qualifications/Responsibilities. cont**	* Bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution with at least four years of laboratory training and/or experience in high complexity testing* **The technical supervisor's training and experience must be in the designated specialty or subspecialty area of service for which the individual is responsible.** ***For laboratories subject to US regulations, alternate qualifications for the following specialty areas can be found in Fed Register. 1992(Feb 28): 7177-7180 [42CFR493.1449]: bacteriology, mycobacteriology, mycology, parasitology, virology, cytology, ophthalmic pathology, dermatopathology, oral pathology, and radioisotope.*** If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed. For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. ***The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.*** The section director, as designated by the laboratory director, must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation andis responsible for the technical and scientific oversight of the laboratory. The section director is responsible for performing and recording competency assessment for high complexity testing. The duties for performing the competency assessment may be delegated, in writing, to individuals meeting general supervisor qualifications for high complexity testing.			https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	CAP Personnel Requirement by Testing Complexity
GEN.53400 cont.R	2	**Section Director (Technical Supervisor) Qualifications/Responsibilities. cont**	Other responsibilities of the technical supervisor include: • Selection of test methodology • Establishment or verification of laboratory test performance specifications • Enrollment and participation in proficiency testing • Establishment of a quality control program to monitor ongoing test performance • Resolution of technical problems and ensuring that remedial actions are taken • Ensuring that patient/client results are not reported until corrective actions are taken and test systems are functioning properly • Identification of training needs For functions that are delegated, such as review of quality control data, assessment of competency, or review of proficiency testing performance, delegation must be in writing and the technical supervisor is responsible to ensure that those functions are properly carried out by a qualified individual.			http://www.cms.hhs.gov/CLIA/downloads/apcsubm.pdf	
			GENERAL SUPERVISORS				

GEN.53600	2	**General Supervisor Qualifications/Responsibilities** Supervisors / general supervisors meet defined qualifications and fulfill expected responsibilities.	NOTE: For high complexity testing, one or more individuals qualified as a general supervisor must be defined on the CAP's Laboratory Personnel Evaluation Roster. Supervisors who do not qualify as laboratory director or section director/technical supervisor must qualify as testing personnel and possess the minimum of a: 1. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology science with at least one year of training and/orexperience in high complexity testing; or 2. Associate degree in a laboratory science or medical technology ***or equivalent education and training as defined in 42CFR493.1489(b)(2)(ii),*** with at least two years of training and/or experience in high complexity testing; or 3. Have previously qualified or could have qualified as a general supervisor prior to ***February 28,*** 1992 *The general supervisor's training and experience must be in the designated discipline or area of service for which the individual is responsible. Requirements for the supervisors/general supervisors of cytopathology and histocompatibility are more stringent and are found in the Cytopathology and Histocompatibility Checklists. If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed. For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. ***The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.***	*✓Records of qualifications including diploma, transcript(s), primary source verification report , equivalency evaluation, or current laboratory personnel license (if required) AND* *✓Certification/registration (if required) and work history in related field AND* *✓Description of current duties and responsibilities*	CLIA Resources ; CLIA Interpretive Guidelines - Refer to HR Department for Pathology - Non Pathology areas must have documentation available.	https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	CAP Personnel Requirement by Testing Complexity
GEN.53600 cont.	2	**General Supervisor. Cont. Qualifications/Responsibilities** Supervisors / general supervisors meet defined qualifications and fulfill expected responsibilities.	The supervisor of high-complexity testing must be accessible to the laboratory as needed for on-site, telephone, or electronic consultation and is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Individuals meeting the qualifications of a general supervisor for high complexity testing may assess the competency of high complexity testing personnel, if this duty is delegated, in writing, by the section director. Other responsibilities of the general supervisor include: ● Resolution of technical problems in accordance with policies and procedures established by the laboratory director or technical supervisor ● Monitoring of test performance ● Ensuring that remedial actions are taken when test systems deviate from the laboratory's established performance specifications ● Providing orientation of testing personnel				
			TECHNICAL AND CLINICAL CONSULTANT				
		The individuals fulfilling these roles must be identified on under the CAP's Laboratory Personnel Evaluation Roster. Within the laboratory's organizational structure, the actual position titles may be different. A qualified laboratory director may also serve as the technical and clinical consultant, and may set position requirements more stringent than defined in the checklist.					
GEN.53625	2	**Technical Consultant Qualifications/Responsibilities.** Technical consultants meet defined qualifications and fulfill expected responsibilities.	NOTE: This requirement applies to all laboratories that are performing any **moderate complexity testing**, it is not applicable if the laboratory only performs high complexity testing. For moderate complexity testing, one or more individuals qualified as a technical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster . The technical consultant (including the laboratory director who serves as a technical consultant) must be qualified by education and experience by one of the following combinations: ● MD or DO, licensed to practice medicine in the jurisdiction where the laboratory is located (if required), with certification in anatomic and/or clinical pathology, by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications equivalent to those required for certification; or ● MD, DO, or DPM, licensed to practice in the jurisdiction where the laboratory is located (if required), with at least one year of training and/or experience in nonwaived testing; or ● Doctoral or master's degree in a chemical, physical, biological or clinical laboratory science from an accredited institutionwith at least one year of training and/or experience in nonwaived testing; or ● Bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with at least two years of training and/orexperience in nonwaived testing. * The technical consultant's training and experience must be in the designated specialty or subspecialty area of service for which thendividual is responsible.	*✓Records of technical qualifications including diploma, transcript, primary source verification report, equivalency evaluation, or current license (if required) AND* *✓Certification/registration (if required) and work history in related field AND* *✓Description of current duties and responsibilities.*	CAP Personnel Requirement by Testing Complexity	https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	
GEN.53625	2	**Technical Consultant Qualifications/Responsibilities. Cont.**	***If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed. For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.*** The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant must be available to the laboratory as needed for telephone, electronic and on-site consultation. Individuals meeting the qualifications of a technical consultant may assess the competency of personnel performing moderate complexity testing. testing,, if this duty is delegated, in writing, by the laboratory director. Other responsibilities of the technical consultant include: ● Establishment or verification of laboratory test performance specifications ● Selection of test methodology ● Enrollment and participation in proficiency testing ● Establishment of a quality control program to monitor ongoing test performance ● Resolution of technical problems and ensuring that remedial actions are taken ● Ensuring that patient / client results are not reported until corrective actions are taken and test systems are functioning properly ● Identification of training needs				
GEN.53650	2	**Clinical Consultant Qualifications/Responsibilities** Clinical consultants meet defined qualifications and fulfill expected responsibilities.	NOTE: This requirement applies to laboratories performing moderate complexity testing and/or high complexity testing. One or more individuals qualified as a clinical consultant must be identified on the CAP's Laboratory Personnel Evaluation Roster . Clinical consultants must be an MD, DO, DPM licensed to practice medicine in the jurisdiction where the laboratory is located (if required) or doctoral scientist certified by an HHS-approved board. If more stringent state or local regulations are in place for clinical consultant qualifications, including requirements for state licensure, they must be followed. ***For laboratories subject to US regulations, credentials for all personnel trained outside of the US must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations should be performed by a nationally recognized organization. The following types of records may also be used to show equivalency:*** ***1) license to practice medicine issued by the state in which the laboratory is located; or*** ***2) laboratory personnel license in states where laboratory personnel licensure is required. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.*** The clinical consultant must be available to provide and ensure that consultation is available on test ordering and interpretation of results relating to specific patient conditions, and for matters relating to the quality of test results reported. The clinical consultant must also ensure that patients' client reports include pertinent information required for interpretation. See ***DIRA*** . 10440, ***DIRA*** .10500 and ***DIRA*** .10700.	*✓Records of clinical consultant qualifications (i.e. a valid medical license AND* *✓Written job description or contract AND* *✓Records of activities performed by the consultant during visits consistent with the job description* *(e.g. meeting minutes, activity logs, signed summaries or data with evidence of review)*	CAP Personnel Requirement by Testing Complexity	https://www.cms.gov/Regulations-and-guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html	
			ALL PERSONNEL				
GEN.54000	2	**Organizational Chart** There is an organizational chart for the laboratory, or a narrative description that describes the reporting relationships among the laboratory's owner or management, the laboratory director, technical supervisor(s), technical consultant(s), clinical consultant(s), and general supervisor(s), as appropriate.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-Quality Management — Quality Management program (QM002)	https://hpo.johnshopkins.edu/hopkins/policies/68/3577/policy_3577.pdf?_=0.5164451701S7	

GEN.54025	2	**Laboratory Personnel Evaluation Roster** The Laboratory Personnel Evaluation Roster is current and accurate and is audited by the laboratory director or designee at least annually for nonwaived testing personnel and personnel fulfilling supervisor roles.	NOTE: The laboratory's audit of the laboratory personnel evaluation roster must include a review of a mixture of the following types of personnel: ● All nonwaived testing personnel hired within the last 12 months (laboratory and non-laboratory) ● Laboratory and non-laboratory (POC, PPT, Radiology, Respiratory, etc.) personnel ● Full and part-time nonwaived testing personnel on all shifts and throughout all departments ● Personnel fulfilling supervisory roles (e.g. laboratory director, technical supervisor, staff pathologist Personnel performing any CLIA-defined duty must be listed on the roster. Personnel performing waived testing only or whose duties are limited to phlebotomy, clerical work or specimen processing are not required to be listed on the Laboratory Personnel Evaluation Roster. Histology personnel that do not perform high-complexity testing are also excluded. All grossing performed in histology is considered high-complexity testing.	✓*Records of completed rosters accurately reflecting personnel AND* ✓*Records of annual audits performed by the laboratory director or designee*			
GEN.54200	1	**Continuing Education** There is a functional continuing laboratory education program adequate to meet the needs of all personnel.		✓*Written policy for continuing laboratory education*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Personnel:Continuing Education Policy (HRDA)	https://hpo.johnshopkins.edu/hopkins/policies/68/7274/policy_7274.pdf?_=0.5788816807357	
GEN.54400	2	**Personnel Records** Personnel records are ***retained*** (in electronic or paper format) and readily available for all testing personnel, supervisory personnel, and other laboratory personnel, including all of the following as applicable: 1. For nonwaived testing and supervisory personnel, copy of academic diploma, transcription or or primary source verification (PSV) report confirming credentials. 2. Laboratory personnel license, if required by state, province, or country 3. Summary of training and experience 4. Certification, if required by state or employer 5. Description of current duties and responsibilities as specified by the laboratory director. a) Procedures the individual is authorized to perform, b) Whether supervision is required for specimen processing, test performance or result reporting, c) Whether supervisory or section director review is required to report patient test results. 6. Records of continuing education 7. Records of radiation exposure where applicable (such as with in vivo radiation testing), but not required for low exposure levels such as certain in-vitro testing 8. Work-related incident and/or accident records 9. Dates of employment	**NOTE 1**: All, items, #1-9 above, apply to nonwaived testing personnel and supervisory personnel (including both laboratory and non-laboratory personnel), as applicable to assigned duties. For other types of laboratory personnel (**eg**. phlebotomists, specimen processors, biorepository personnel), items #2-9 apply, as applicable to their assigned duties. These personnel must meet the institution's defined qualifications at the positions held and have appropriate state licensure, where applicable. **NOTE 2**:For laboratories subject to US regulations: nonwaived testing and supervisory personnel records must demonstrate that each individual meets the required educational qualifications for the position held. A state laboratory personnel license specific to the role and specialty of testing may be used instead of a diploma, transcripts, or a PSV report if the laboratory is located in a state that requires laboratory personnel licensure (licensure for other disciplines, such as nursing, radiology, orrespiratory therapy are not acceptable). If a diploma orprimary source verification (PSV) report does not specify one of the required areas of study (biology, chemistry, etc.) or are for training obtained outside of the US, there must be records showing that qualifications are met using other acceptable means (eg. transcripts, equivalency evaluation). The training and qualifications of all personnel trained outside of the US must be evaluated to determine equivalency to an education obtained in the United States, with records of the evaluation available in the personnel file. Equivalency evaluations must be performed by a nationally recognized organization, such as the **National Association Credential Evaluation Services, Inc. (NACES)** (http://www.naces.org) and the **Association of International Credential Evaluators, Inc. (AICE)** (http://www.aice-eval.org). ***The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required.*** Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.	✓*Copies of diplomas, transcripts, equivalency evaluation, or current laboratory personnel* *licensure (if required) accessible at the laboratory OR* ✓*Policy for use of primary source verification reports, with criteria for acceptance, if used AND* ✓*Primary source verification reports with required elements*		(NACES) http://www.naces.org/ (AICE) http://aice-eval.org/	
GEN.54400 R cont		**Personnel Records (cont.)**	If PSV reports are used,the laboratory must have a defined system for reviewing the reports, with written criteria for acceptance. PSV is typically performed by a third-party agent or company that directly contacts institutions and former employers to verify training and experience, such as diplomas, board certification, licensure, and reported work history. PSV reports confirming the required qualifications may be retained in lieu of obtaining paper copies of these records. The credentialing systems used by the Department of Veterans Affairs (i.e. VetPro Credentialing System) and Department of Defense may be used to document educational qualifications. Records must be available upon request. While certification of testing personnel by a professional organization, such as ASCP or AMT, is highly desirable, records of the certification alone are not considered adequate to demonstrate that educational qualifications have been met. **NOTE 3**: For laboratories not subject to US regulations, laboratories may authenticate educational achievement according to prevailing governmental rules.				
GEN.54750	2	**Nonwaived Testing Personnel Qualifications** ***All nonwaivedtesting personnel meet the following requirements*** 1. Personnel performing high complexity testing must have a minimum of one of the following: ● Bachelor'sdegree in a chemical, biological, or clinical laboratory science or medical technology from an accredited institution; or ● Associate degree in a laboratory science (chemical or biological science) ormedical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulation 42CFR493.1489. (see NOTE 2). ● ***Meet other provisions defined in 42CFR493.1489(b)(2)(B)(4) or 42CFR493.1489(b)(2)(B)(5)(i) for personnel performing high complexity testing on or before April 24, 1995 (refer to the CLIA regulations for more details)*** 2. Personnel performing moderate complexity testing, including non-laboratory personnel, must have a minimum one of the following: ● Associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; or ● High school graduate or equivalent and have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist; or	**NOTE 1**: Laboratory and non-laboratory (eg. nurses, respiratory therapists, radiologic technologists, and medical assistants) testing personnel must meet the qualifications appropriate to the complexity of testing performed. GEN.54400 contains the specific requirements for the types of records that must be ***retained*** in the personnel file to demonstrate compliance. Additional information for assessing personnel qualifications is available at the following link: O o CAP Personnel Requirement by Testing Complexity **NOTE 2**: For high complexity testing, equivalent laboratory training and experience includes the following: ● 60 semester hours or equivalent from an accredited institution that, at a minimum, includes either 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination; AND ● Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLS, or other organization approved by HHS (note that this training may be included in the 60 semester hours listed above), OR at least three months documented laboratory training in each specialty in which the individual performs high complexity testing. **NOTE 3**: For US Department of Defense laboratories, effective May 29, 2014, newly hired high complexity testing personnel must have either ● A minimum of an associate degree in a biological or chemical science or medical laboratory technology from an accredited institution AND be certified by the ASCP, AMT or other organization deemed comparable by DASD(HA) or their designee (CCLM) as an MLT or MT/MLS; OR ● Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and currently hold the military enlisted occupational specialty of medical laboratory specialist (laboratory technician).	✓*Records of qualifications including diploma, transcript, equivalency evaluation, or current laboratory personnel license (if required) AND* ✓*Work history in related field*			
cont. GEN.54750		**Testing Personnel Qualifications** **All testing personnel meet the following requirements** ● High school diploma or equivalent and have a record of training defined in the CLIA regulation 42CFR493.1423 (see NOTE 4)High school diploma or equivalent and record of training defined in the CLIA regulation 42CFR493.1423 (see NOTE 4)	**NOTE 4**: For moderate complexity testing personnel qualifying with a high school diploma or equivalent qualifications only, training records must demonstrate skills for the following: ● Specimen collection, including patient preparation, labeling, handling, preservation, processing, transportation, and storage of specimens, as applicable; ● Implementation of all laboratory procedures; ● Performance of each test method and for proper instrument use; ● Preventive maintenance, troubleshooting and calibration procedures for each test performed; ● Working knowledge of reagent stability and storage; ● Implementation of quality control policies and procedures; ● An awareness of interferences and other factors that influence test results; and ● Assessment and verification of the validity oftest results, including the performance of quality control prior to reporting results. **NOTE 5**: Students gaining experience in the field must work under the direct supervision of a qualified individual. **NOTE 6**: If more stringent state or local regulations are in place for personnel qualifications, including requirements for state licensure, they must be followed				
GEN.55400	1	**Visual Color Discrimination** Technical personnel are tested for visual color discrimination.	NOTE: Technologists performing testing or other tasks that require color discrimination should be evaluated for difficulty with visual color discrimination. Evaluation is not required for personnel who do not perform such functions. Evaluation limited to discrimination of those colored items pertinent to the job is sufficient.	✓*Record of color discrimination testing OR functional assessment, if indicated*	Occupational Health Dept. Performs testing	http://www.hopkinsmedicine.org/hr/occupational_health/	All color blind testing is performed at Pre-employment screening. Occupational health @ 410-614-2485.
GEN.55450	2	***Personnel* Training** There are records that all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job.	NOTE: For testing personnel, prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance. The records must cover all testing performed by each individual. Training records must be *retained* for a minimum of two years (five years for transfusion medicine). After the initial two-year (or five-year) period, records of successful ongoing competency assessment may be used in lieu of training recordsto demonstrate compliance with this requirement. Retraining must occur when problems are identified with personnel performance.				

GEN.55499	2	**Competency Assessment - Waived Testing** The competency of personnel performing waived testing is assessed at the required frequency.	NOTE: Prior to starting patient /client testing and prior to reporting results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450. After an individual has performed his/her duties for one year, competency must be assessed annually.Retraining and reassessment of employee competency must occur when problems are identified with an individual's performance. Records of competency assessment may be *retained* centrally within a healthcare system, but must be available upon request. The laboratory director may determine how competency will be assessed for personnel performing waived testing at multiple test sites (same CAP/CLIA number) or laboratories within the healthcare system (different CAP/CLIA numbers). If there are variations on how a test is performed at different test sites or laboratories, those variations must be included in the competency assessment specific to the site or laboratory. For waived test systems, it is not necessary to assess all six elements listed below at each assessment event. The POCT program may select which elements to assess Elements of competency assessment include but are not limited to: 1. Direct observations of routine test performance, including, as applicable, patient/sample identification and preparation; and specimen collection, handling, processing and testing 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results	*✓Written procedure defining the method and frequency for assessing competency.AND* *✓Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required frequency*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Competency Assessment Policy (HR006)	https://hpo.johnshopkins.edu/hopkins/policies/68/8986/policy_8986.pdf? -0.93542245367	
GEN.55499	2	**Competency Assessment (continuation)**	3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance and function checks, as applicable 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Evaluation of problem-solving skills. If more stringent state or local regulations are in place for competency assessment of waived testing, they must be followed.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Competency Assessment Policy (HR006)	https://hpo.johnshopkins.edu/hopkins/policies/68/8986/policy_8986.pdf? -0.93542245367	
GEN.55500	2	**Competency Assessment** - Nonwaived Testing The competency of personnel performing nonwaived testing is assessed at the required frequency at the laboratory (CAP/CLIA number) where testing is performed	***NOTE:*** Prior to starting patient/client testing and prior to reporting results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required in GEN.55450 Competency must be assessed at the following frequency: ● During the first year of an individual's duties, competency must be assessed at least semiannually; ● After an individual has performed his/her duties for one year, competency must be assessed at least annually ● Retraining and reassessment of competency must also occur when problems are identified with an individual's performance. Records of competency assessment may be *retained* centrally within a healthcare system, but must be available upon request. Competency of nonwaived testing personnel must be assessed at the laboratory where testing is performed (CAP/CLIA number). If there are variations on how a test is performed at different test sites, those variations must be included in the competency assessment specific to the site or laboratory	*✓Records of competency assessment for new and existing testing personnel reflecting the specific skills assessed and the method of evaluation at the required frequency AND ✓ Written procedure defining the method and frequency for assessing competency*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Competency Assessment Policy (HR006)	https://hpo.johnshopkins.edu/pathology-enterprise/policies/905/44267/policy_44267.pdf? -0.33888669279? -0.93098048510S	
GEN.55500	2	**Competency Assessment - Nonwaived Testing -cont.**	Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an *element* is not applicable to the test system. Elements of competency assessment include but are not limited to: 1.Direct observations of routine test performance, including, as applicable, patient/sample identification and preparation; and specimen collection, handling, processing and testing 2.Monitoring the recording and reporting of test results, including, as applicable, reporting critical results 3.Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4.Direct observation of performance of instrument maintenance and function checks 5.Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6.Evaluation of problem-solving skills The laboratory must identify the test systems that testing personnel use to generate test results. A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single use and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte. In many situations, tests performed on the same analyzer may be considered one test system; however, if there are any tests with unique aspects, problems or procedures within the same testing platform (eg. pretreatment of samples prior to analysis), competency must be assessed as a separate test system to ensure personnel are performing those aspects correctly.				
GEN.55500	2	**Competency Assessment - Nonwaived Testing -cont.**	Many of the elements of competency assessment are performed during routine review of personnel throughout the year. Records of these elements, including adherence to laboratory policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed during routine review by an individual qualified to assess competency for the complexity of testing performed, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment during routine review may be recorded using a checklist				
GEN.55510	2	**Qualifications of Individuals Assessing Competency** Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed	**NOTE:** The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the assessor vary by the complexity of the testing. For laboratories subject to US regulations, the following include the minimum qualifications for assessors: ● High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications ● Moderate complexity testing: Technical consultant or individual meeting those qualifications ● Waived testing: May be determined by the laboratory director For laboratories not subject to US regulations, individuals assessing competency must, at minimum, meet the personnel qualifications to perform the test and be knowledgeable on the testing performed.	*✓Policy or statement signed by the laboratory director authorizing individuals by name or job title to perform competency assessment AND* *✓Records of competency assessments performed by qualified individuals*			
GEN.55525	2	**Performance Assessment of Supervisors/Consultants** The performance of section directors/technical supervisors, general supervisors, technical consultants, ***and clinical consultants*** is assessed and satisfactory.	NOTE: All responsibilities of section directors, technical supervisors, technical consultants, ***general supervisors, and clinical consultantsgeneral supervisors, and clinical consultants*** must be delegated by the laboratory director in writing. The frequency for assessments must be defined in laboratory policy and be appropriate to the size, test menu, and complexity of the facility. The assessment may take the form of a checklist or otherrecord of performance of responsibilities, as defined by the individual's job description. ***Unsatisfactory performance must be addressed in a corrective action plan.*** If assessment of these individuals is not performed or there are inadequate or inconsistent records, a deficiency should also be cited for ***DRA*** .11425 (Director Responsibility - Delegation of Functions) in the Director Assessment Checklist. If the individuals in these roles are also performing nonwaived patient testing, competency assessment requirements for testing personnel (GEN.55500) also apply, including all six elements of competency ***at the required frequencies.***	*✓Job descriptions that list regulatory responsibilities AND* *✓Records of performance assessment ✓ Written policy for performance assessment*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Competency Assessment Policy (HR006)	https://hpo.johnshopkins.edu/hopkins/policies/68/8986/policy_8986.pdf? -0.93542245367	
GEN.57000	2	**Competency Corrective Action** If ***testing personnel fail*** to demonstrate satisfactory performance on the competency assessment, the laboratory ***follows*** a plan of corrective action to retrain and reassess competency.	NOTE: If it is determined that there are gaps in the individual's knowledge, the employee should be re-educated and allowed to retake the portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.	*✓Records of corrective action to include evidence of retraining and reassessment of competency* *✓Written procedure for competency assessment corrective action*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel — HPO; Competency Assessment Policy (HR006)	https://hpo.johnshopkins.edu/hopkins/policies/68/8986/policy_8986.pdf? -0.93542245367	
			BIOREPOSITORY PERSONNEL ***This section contains requirements that only apply to biorepositories. These requirements are in addition to the other applicable requirements in the All Personnel section.***				
GEN.57010	2	**Leadership/Management Qualifications - Biorepositories Only** Leadership/management have qualifications sufficient for the level of service of the biorepository.					
GEN.57020	1	**Description of Duties - Biorepositories Only** 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.57030	2	**Staff Qualifications - Biorepositories Only** The biorepository director must define the minimum qualifications for each role in the biorepository based on the level of service of the biorepository.		*✓Written description of minimum qualifications*			
GEN.57040	2	**Biorepository Personnel Evaluation Roster - Biorepositories Only** The Biorepository Personnel Evaluation Roster is current and accurate and is audited by the biorepository director or designee at least annually.		*✓Records of completed rosters accurately reflecting personnel AND* *✓Records of annual audits performed by the biorepository director or designee*			
GEN.57050	2	**Competency Assessment - Biorepositories Only** 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.55450 After an individual has performed his/her duties for one year, competency must be assessed annually. Retraining and reassessment of competency must occur when problems are identified with an individual's performance. 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.	● *✓Records of competency assessment for new and existing personnel reflecting the specificskills assessed, the method of evaluation*			
			PHYSICAL FACILITIES				
			SPACE				
GEN.59980	1	***Restricted Laboratory Access*** The laboratory has a written policy for restricting access to the laboratory to authorized individuals.	***NOTE:*** This may be accomplished through the use of access codes (security codes, user codes), locks, or other processes (eg, policies and procedures) that limit access to authorized personnel. Access authorization must be maintained and current (eg, inactivated when employment of an authorized individual ends). The written policy should include: ● Who is authorized to enter the laboratory on a routine basis (eg, laboratory staff, other employees, etc.) and ● How non-laboratory personnel (eg, visitors, vendors, contractors) can obtain access on a temporary basis				
GEN.60000	2	**Adequate Space** The general laboratory has adequate, conveniently located space so the quality of work, safety of personnel, and patient care services are not compromised					
GEN.60100	1	**Adequate Space** All of the following areas have sufficient space and are located so there is no hindrance to the work. 1. Laboratory director 2. Staff pathologists and residents 3. Clerical staff 4. Section supervisors 5. Outpatient/ambulatory waiting and reception 6. Lavatories 7. Library, conference and meeting room 8. Personnel lounge and lockers					
GEN.60150	1	**Adequate Space** There is adequate space for: 1. Technical (bench) work 2. Instruments and equipment 3. Storage (records, slides, tissue, etc.) 4. Refrigerator/freezer storage 5. Media preparation, as applicable 6. Accessioning of potentially biohazardous specimens, as applicable 7. Radionuclide storage, as applicable 8. Microscopy and imaging, as applicable					
		ENVIRONMENT ***Ambient or room temperature and humidity must be controlled to minimize evaporation of specimens andreagents, to provide proper growth conditions for room temperature incubation of cultures, and not to interfere with the performance of electronic instruments.***					
GEN.60250	1	**Working Environment** The following are adequate for the facility. 1. Lighting 2. Water taps, sinks, drains 3. Electrical outlets 4. Ventilation 5. Gas and suction, when applicable					
GEN.60275		**HVAC - Biorepositories Only** HVAC units, if present, are properly serviced and functioning to maintain appropriate compressor activity.		*✓Records of maintenance*			
GEN.61300	1	**Climate Control** The room temperature and humidity are adequately controlled in all seasons.		*✓Temperature and humidity records, if specific ranges are required for instrument and/or reagent use*			
GEN.61350	1	**Direct Sunlight** Exposure to direct sunlight is minimized.	NOTE: Direct sunlight should be avoided because of its extreme variability and the need for low light levels necessary to observe various computer consoles, etc. Lighting control should be sectionalized so general levels of illumination can be controlled in areas of the room, if desired				
GEN.61400 R	2	**Hallway Obstructions** Passageways are unobstructed.			Supporting Policy HSE 026	https://hgo.johnshopkins.edu/ts/policies/156/10920/policy_10920.pdf?_=0.14645836073	
GEN.61500	1	**Environment Maintenance** Floors, walls and ceilings are clean and well-maintained.					Lab staff are able to contact EVS when needed at 955-8300
GEN.61600	1	**Environment Maintenance** Bench tops, cupboards, drawers and sinks are clean and well-maintained.					
			COMMUNICATION ***Communications within the laboratory should be appropriate for the size and scope of the laboratory. Messages should be transferred efficiently to all sections.***				
GEN.61750	1	**Hand-Off Communication** The laboratory implements a written procedure for effective "hand-off" communication.	NOTE: The laboratory **must** have a written procedure for communicating information about pending specimens, tests and patient care issues when responsibility is "handed off" from one person to another, such as at a change in shift, or when the responsibility for a case is transferred from one pathologist to another. The procedure should include provision for asking and responding to questions.	*✓Logs or message boards showing communication between shifts*			Laboratories to follow their hand off communication policy
GEN.61800	1	**Telephone/Computer Locations** Telephones and computer terminals are conveniently located.					

			INVENTORY AND STORAGE OF SUPPLIES				
GEN.61900	1	**Inventory Control** There is an effective supply inventory control system in operation.	NOTE: An effective inventory control system minimizes emergency requisitions and shortages of supplies.				
GEN.62000	1	**Intralaboratory Storage** The intralaboratory storage area sufficient and free of clutter.					
GEN.62020	2	**Centralized Reagent and Supply Storage** If reagents and supplies are stored in a centralized area outside of the laboratory, they are stored and handled in accordance with the manufacturer's instructions, and temperatures are checked and recorded daily using a calibrated thermometer.	***NOTE:*** If the manufacturer defines a required storage temperature range, the temperature of the storage area must be monitored daily. "Daily" means every day (seven days per week, 52 weeks per year). Acceptable ranges must be defined and corrective action must be taken when temperatures fall out of the acceptable range for the specified reagent or supply item. Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording the temperature(s) must be recorded (the initials of the individual are adequate). If an automated (including remote) temperature monitoring system is used instead of manual temperature monitoring, personnel must have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. Records must demonstrate the daily functionality of the system. If a minimum/maximum thermometer is used to perform continuous monitoring of temperaturesbetween daily temperature readings or following a laboratory downtime (e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.	*✓Temperature log or records with defined acceptable range including appropriate corrective*			
			POWER				
GEN.66100	2	**Emergency Power** Emergency power is adequate for the functioning of the laboratory	***NOTE:*** Emergency power supply must be adequate for refrigerators, freezers, incubators, etc., to ensure preservation of patient specimens. Depending on the type of testing performed in the laboratory, emergency power may also be required for the preservation of reagents, the operation of laboratory instruments, and the functioning of the data processing system.		Corporate and Administrative Policy manual Emergency Preparedness -Facility: Electric power outage (EP005)	http://www.insidehopkinsmedicine.org/hpo/policies/52/1320/policy_1320.pdf	
GEN.66110	2	**Emergency Power Load Testing - Biorepositories Only** 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.		Corporate and Administrative Policy manual Emergency Preparedness -Facility: Electric power outage (EP005)	http://www.insidehopkinsmedicine.org/hpo/policies/52/1320/policy_1320.pdf	
GEN.66120	2	**Contingency Plans - Biorepositories Only** 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.		*✓Written contingency plan AND* *✓Schedule of fuel deliveries*			
			Laboratory Safety				
			SAFETY POLICIES , PROCEDURES , AND RECORDS ***Requirements in this section cover the general safety program for the entire laboratory and must be answered for all laboratory sections. Non-compliance with any of these requirements in any one section of the laboratory represents a deficiency for the entire laboratory. Requirements related to safety features specific to an individual section will be found in the checklist that section. With respect to fire safety, if a checklist requirement conflicts with regulations of the Authority Having Jurisdiction (i.e. state and local fire codes), the regulations of the Authority Having Jurisdiction take precedence.***				
GEN.73200	2	**Safety Policy and Procedure Approval** The director or designee review and approve all changes to the safety policies and procedures before implementation.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	
GEN. 73300	2	**Safety Policy and Procedure Training** There are records for the training of all personnel in safety policies and procedures.	NOTE:A system to ensure that all personnel have read the policies and procedures is required and must form a portion of the orientation program for new personnel. Posting of specific warnings or hazards as appropriate is urged.	*✓Records of personnel review of safety procedures*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775
GEN.73400	2	**Safe Work Practices Review** There are **records of** periodic review (at least annually) of safe work practices to reduce hazards.	NOTE: Review must include bloodborne hazard control and chemical hygiene. If the review identifies a problem, the laboratory must investigate the cause and consider if modifications are needed to the safety policies and procedures to prevent reoccurrence of the problem or mitigate potential risk.	*✓Safety committee minutes OR records of regular safety inspections OR incident reports and statistics OR another method defined by the laboratory director*		https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	Safety records will be made available by COJ office.
GEN.73500	2	**Lab Accidents** There are written policies and procedures for the reporting and recording of all laboratory accidents resulting in property damage or involving spillage of hazardous substances.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775
GEN.73600	2	**Occupational Injuries** There are written policies and procedures for the reporting of all occupational injuries or illnesses that require medical treatment (except first aid).	NOTE:For U.S. laboratories subject to OSHA regulations, all workplace fatalities must be reported to the Occupational Safety and Health Administration (OSHA) within eight hours and work-related in-patient hospitalizations, amputations, or losses of an eye within 24 hours.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) Sect. VI // JHI Safety Manual: Incident and Injury Reporting - HSE502	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10901/policy_10901.pdf?_=0.180870701895
GEN.73700	2	**Occupational Injury Evaluation** An evaluation of laboratory accident and occupational injury/illness reports is incorporated into the laboratory's quality management program to avoid recurrence.		*✓Records of report evaluation OR committee minutes with records of discussion*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10901/policy_10901.pdf?_=0.180870701895
GEN.73800	2	**Emergency Preparedness** There are written policies and procedures defining the role and responsibilities of the laboratory in emergency preparedness for harmful or destructive events or disasters.	***NOTE:*** The specific elements to be included in the emergency preparedness plan must be based on a risk assessment using an "all-hazards" approach to evaluate the types of hazards most likely to occur that would potentially disrupt services. Written policies and procedures must be developed to support the execution of the laboratory's emergency response plan and the path of workflow, including a communication plan. Laboratories located within a healthcare facility or integrated health system may participate in development of a facility or system-wide emergency preparedness plan rather than an individual laboratory plan, but must ensure that policies and procedures for the plan are clearly defined and address the relevant site-specific risks. Examples of events that may be addressed in the emergency preparedness plan include situations such as unexpected system failures (e.g. HVAC, water, communication, computer system), power failures, natural disasters (e.g. tornado, hurricane, earthquake, fire, flood), emerging public health threats, cyber-attacks, terrorist events, or workplace violence.		Pathology Diaster Plan EM001, and Business Continuity Plan; Hospital Emergency Preparedness,	https://hpo.johnshopkins.edu/hopkins/policies/68/5407/policy_5407.pdf?_=0.328493517412	
GEN.73900	2	**Evacuation Plan** There is a written comprehensive,and workable evacuation plan specific for the laboratory.	NOTE: 1. This plan must cover all personnel, patients and visitors, and must address the special needs of persons with disabilities. Evacuation routes must be clearly marked (Posting evacuation routes is optional) / 2. Emergency lighting is adequate for safe evacuation of the laboratory/		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) , HSE408 Evacuation Plan	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10957/policy_10957.pdf?_=0.967466035918
			Infection Prevention and Control				
GEN.74000 ®	2	**Infection Control** The laboratory follows written policies and procedures for infection control that comply with national, ***federal***, state, ***(or provincial)*** , and local guidelines on occupational exposure to bloodborne pathogens and other infectious pathogen, and to the institution's exposure control plan.	NOTE:Universal or standard precautions must be used when handling all blood and potentially infectious, such as body fluid specimens and unfixed tissues. The term 'universal precautions' refers to a concept of bloodborne disease control requiring all human blood and other potentially infectious materials to be treated as if infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived 'low risk' status of a patient or patient population. Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These latter terms define all body fluids and substances as infectious. All personnel must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with blood or other body fluids is anticipated. For laboratories subject to US regulations, policies and procedures must comply with the OSHA Standard on Bloodborne Pathogens. The institution's exposure control plan must address potential hazards that laboratory visitors may encounter.	*✓Safety manual AND* *✓Records of universal precaution training for all personnel expected to have contact with infectious materials*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -— HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) pg. 9 // JHH Safety manual- Bloodborne Pathogen Exposure Control Plan HSE 501, training in personnel files	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10973/policy_10973.pdf

GEN.74050 N	2	**Specimen Handling/Processing** The laboratory safely handles specimens suspected to contain highly infectious pathogens.	NOTE: Laboratories should review national, federal, state (or provincial), and local guidelines for the handling of samples from patients suspected to have high risk pathogens such as avian influenza, MERS coronavirus, SARS coronavirus, or COVID-19 coronavirus.				
GEN.74100 R	2	**PPE Provision and Usage** Appropriate personal protective equipment (gloves, gowns, masks and eye protectors, etc.) is provided and maintained in a sanitary and reliable condition in all work areas whenever blood and other potentially infectious materials are handled and in circumstances during which exposure is likely to occur.	NOTE: Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious materials to pass through or reach an individual's the employee's work clothes, skin, eyes, mouth, or other mucous membranes under normal conditions of use. In addition to fluid-resistant gowns, aprons may be required if exposure to large volumes of body fluids is anticipated. OSHA requires unpowdered gloves to be worn with each patient contact and changed after contact when performing vascular access, except when drawing voluntary blood donors./. Hands must be cleaned after glove removal using an effective antimicrobial method. PPE must be made available to laboratory visitors, as applicable.	https://hpo.johnshopkins.edu/hse/policies/156/10903/policy_10903.pdf?_=0.011591150381 2	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: A-Johns Hopkins Medical Laboratories Safety Manual (LES004) Section IV Protective Devices for Health Care Worker-HSE006.Use of Protective Eye and Face Equipment-HSE007	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	https://hpo.johnshopkins.edu/hse/policies/156/10902/policy_10902.pdf?_=0.500482483881
GEN.74200	2	**PPE Instruction** Personnel are instructed in the proper use of personal protective clothing/equipment eg. gloves, gowns, masks, eye protectors, footwear, etc.), and records are **retained** .	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.	✓*Written policy for the use of PPE for specific tasks AND* ✓*Records of personnel training for PPE*	Training forms are maintained by Laboratory and HSE	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	http://www.hopkinsmedicine.org/hse/hsms/eyewash_training.pdf
GEN.74250 R	**2**	**Hand Hygiene** All personnel remove gloves and clean hands using an effective antimicrobial method following contact with blood or other potentially infectious materials or after each patient contact.					
GEN.74300	2	**Manual Manipulation Needles** There is a written policy that prohibits the recapping, purposeful bending, breaking, removing from disposable syringes, or other manual manipulations of needles.	NOTE:Re-sheathing instruments or self-sheathing needles may be used to prevent recapping of needles by hand.		HSE 501 Bloodborne Pathogen Exposure Plan, and HSE805-Laboratory Waste Disposal- section - SHARPS DISPOSAL.	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	https://hpo.johnshopkins.edu/hse/policies/156/10973/policy_10973.pdf?_=0.0179430069011
GEN.74400 R	2	**Eating/Mouth Pipetting** There is a written policy policy that prohibits smoking, vaping, eating, gum chewing, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) General Safety	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	
GEN.74500 R	2	**Specimen Transport Procedures** The laboratory receives handles, and transport specimens (blood, and other potentially infectious materials) in appropriately labeled and well-constructed containers with secure lids to prevent leakage during transport.	NOTE:Specimens sent through pneumatic tube systems must be sealed in fluid-tight bags. If pneumatic tube systems are used for transporting specimens, the laboratory must have procedures to respond to a spill within the tube, including appropriate decontamination measures.		Facilities procedures for Pneumatic tube spills are located HPO-ICPM, Pneumatic Tube System PAS006	https://hpo.johnshopkins.edu/hopkins/policies/39/103/policy_103.pdf?_=0.8853484814636	
GEN.74600 R	2	**Spill Handling** The Laboratory follows written procedures for handling spills of blood and other potentially infectious materials.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) < Appendix D, Spill Response	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	
GEN.74700	2	**Hepatitis B Vaccinations** Personnel reasonably expected to have direct contact with blood and other potentially infectious materials are identified offered hepatitis B vaccinations free of charge. Personnel that decline the vaccine sign a declination form.		✓*Written policy offering the hepatitis B vaccination to personnel*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) General Safety, pg. 4, HSE 003 Immunization covered by Occupational Health	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	https://hpo.johnshopkins.edu/hse/policy/156/10900/policy_10900.pdf?_=0.677398478388
GEN.74800	2	**Viral Exposure** There is a policy for follow-up after possible and known percutaneous, mucous membrane or abraded skin exposure to HIV, HBV or HCV that includes the following elements. 1. HIV, HBV and HCV testing of the source patient after consent is obtained 2. Appropriate clinical and serologic evaluation of ***personnel*** 3. Consideration of appropriate prophylaxis for personnel acutely exposed to HIV, HBV or HCV, based upon medical indications, the serologic status and the ***individual's*** informed consent 4. Reporting of the exposure as required by law		✓*Records of exposure follow-up consistent with policy*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	
GEN.74900 R	2	**Tuberculosis (TB) Exposure Plan** The laboratory follows written tuberculosis exposure control plan that includes the following: ● TB exposure screening at defined intervals for all personnel who may have occupational exposure to tuberculosis. ● Use of engineering and practice controls for hazardous activities that may potentially aerosolize Mycobacterium tuberculosis	NOTE: ***This requirement does not apply to laboratories that have no patient exposure or do not handle potentially infectious specimens (e.g. Mohs or pathology interpretation only).*** The plan must define when exposure screen will be performed and who may have occupational exposure to tuberculosis. The CAP (~~2018 CDC recommendations~~) New the for tuberculosis screening, testing, and treatment for health care personnel published in Morbidity and Mortality Weekly when developing their plan. At minimum, the laboratory must perform exposure screening at the following intervals for personnel who may have occupational exposure: ● Baseline screening and individual preplacement TB risk assessment ● Post exposure screening (known exposure to a person or specimen(s) with potentially infectious TB disease without use of adequate engineering controls and/or personal protection as defined by laboratory policy) ● Serial screening, as applicable ● As required by state and/or local regulations Serial screening (eg, annual) is not indicated for personnel without latent TB infection if there is no known exposure or in settings where there is no evidence of ongoing TB transmission. It is indicated for personnel at increased occupational risk for TB exposure or in settings where transmission has occurred in the past. Laboratories must consider these risk factors when defining policies for serial testing. The CDC recommends annual TB education for all personnel, including information about TB exposure risks. Engineering and work practice controls are required for hazardous activities that potentially may aerosolize Mycobacterium tuberculosis, such as the handling of unfixed tissues in surgical pathology or autopsies, and processing specimens in the microbiology section from patients with suspected or confirmed tuberculosis, and handling mycobacterial cultures.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) **Next link**- Hospital safety manual: Airborne Pathogen Control Program- HSE-601	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.6966351087752	https://hpo.johnshopkins.edu/hse/policy/156/10979/policy_10979.pdf?_=0.6681598005152
GEN.74900 cont. R	2	**Tuberculosis** (TB) Exposure Plan *(cont.)*	If respiratory protection is needed because of potential exposure to an infectious agent by aerosol or droplet, personnel must use either a properly fit-tested filter respirator (N-95 or higher) or a powered air-purifying respirator (PAPR) equipped with high efficiency particulate air (HEPA) filters. Annual fit testing is required for the use of any tight-fitting respirator. For laboratories subject to US regulations, the filter respirator must be NIOSH-approved				
GEN.75000	2	**Sterilizing Device Monitoring** All sterilizing devices are monitored periodically with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use.	NOTE: Each sterilizing device must be monitored periodically with a biologic indicator to measure the effectiveness of sterility. Chemical indicators that reflect sporicidal conditions may be used. The test must be performed under conditions that simulate actual use. One recommended method is to wrap the Bacillus stearothermophilus spore indicator strip in packaging identical to that used for a production run, and to include the test package with an actual sterilization procedure. Weekly monitoring is recommended.	✓*Written procedure for monitoring sterilizing devices AND* ✓*Records of monitoring at defined frequency*	Interdisciplinary Clinical Practice Manual. Sterilization and Disinfection of products-HEIC-IPC038	https://hpo.johnshopkins.edu/hopkins/policies/39/9527/policy_9527.pdf?_=0.9608361241317	

			FIRE PREVENTION AND PROTECTION ***Fire codes are based on a number of variables, such as the type of occupancy, its architecture, and the materials for its construction. The local fire authority is ultimately responsible for fire protection and prevention. Any site-specific arrangements that vary from what is defined in the Fire Prevention and Detection requirements below must be approved by that authority, with records for the approval retained by the laboratory. These records may be presented to an inspector to demonstrate compliance with the variance.***				
GEN.75100	*2*	**Fire Prevention Policies and Procedures** 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.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) **// JH Safety Manual** HSE401	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10951/policy_10951.pdf?_=0.738258718408
GEN.75200	*2*	**Fire Separation** The laboratory is properly separated from inpatient areas and/or provided with automatic fire extinguishing (AFE) systems.	NOTE: For those facilities with inpatients, where the laboratory is separated by **two** -hour construction (rated at 1.5 hours) and Class B self-closing doors (SCD), no AFE system is required. An AFE system is required for those laboratories separated from inpatient areas by **one**-hour construction and class C SCD if flammable and combustible liquids are stored in bulk. An AFE system is always required if there are unattended laboratory operations employing flammable or combustible reagents. "Stored in bulk" means more than **two** gallons **(7.5 L)** of Class I, II, and IIIA liquids in safety cabinets and safety cans per 100**ft² (9.2 m²),** or half that amount if not in safety containers. The following are the definitions of these Classes Class I flammable: any liquid that has a closed-cup flash point below 37.8°C and a Reid vapor pressure not exceeding 2068.6 mm Hg at 37.8°C as determined by ASTM D 323 Class II combustible: any liquid that has a flash point at or above 37.8°C and below 60°C Class IIA combustible: any liquid that has a flash point at or above 60°C but below 93°C		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) **; // JH Safety manual** HSE 401-413	https://hpo.johnshopkins.edu/hse/?event=section&sectionId=A897CF180EE3636D77B0B8243F49CF40	https://hpo.johnshopkins.edu/hse/
GEN.75300	*2*	**Fire Exit** Each room larger than 1000 **ft² (92.9 m²),** , or in which major fire hazards exist, has at least **two** exit access doors remote from each other, one of which opens directly into an exit route.			DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: A-Administrative; 6a Laboratory Safety manual -sections IV **// JH Safety manual**.HSE-401-413	https://hpo.johnshopkins.edu/hse/?event=section&sectionId=A897CF180EE3636D77B0B8243F49CF40	https://hpo.johnshopkins.edu/hse/
GEN.75400	*2*	**Fire Safety Training** ***New personnel are trained on fire*** safety with a fire safety review conducted at least annually.	NOTE: ***There*** must be ***records of fire safety training*** for all ***personnel*** to show that they have been instructed on use and response to fire alarms and to execute duties as outlined in the fire safety plan. While fire exit drills are not required, physical evaluation of the escape routes must be performed annually, to ensure that fire exit corridors and stairwells are clear and that all fire exit doors open properly (i.e., not rusted shut, blocked or locked). Paper or computerized testing of an individual's fire safety knowledge on the fire safety plan is acceptable; all personnel must participate at least once a year.	*✓Records of participation for all employees in fire safety plan review at least annually (e.g. personnel roster with dates of participation)*	Annual training required	https://www.hopkinsmedicine.org/hse/training/	
GEN.75500	*2*	**Fire Detection/Alarm** There is an automatic fire detection and alarm system.	NOTE: 1. The system must connect to the facility's overall system, where such a system exists. It must sound an immediate alarm in the event of smoke or fire. 2. The fire alarm is audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms. 3. Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	
GEN.75600	*2*	**Fire Alarm Station** There is a fire alarm station in or near the laboratory.	NOTE: Alarm stations must be visible, unobstructed, and accessible.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) **// JHH Safety manual. HSE 401-413**	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/
GEN.75700	*2*	**Fire Extinguishers** 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.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	
GEN.75800	*2*	**Fire Extinguishers** If the fire safety plan includes use of fire extinguishers, personnel are instructed in the use of portable fire extinguishers	NOTE: It is strongly recommended that instruction include actual operation of extinguishers that might be used in the event of a fire, unless prohibited by the local fire authority	*✓Records for fire extinguisher training*	Incipient Fire Response Team for Johns Hopkins Institutions, prohibit the use of extinguishers by staff, Policy HSE 409	https://hpo.johnshopkins.edu/hse/policies/156/10958/policy_10958.pdf?_=0.9322820172363	
			ELECTRICAL SAFETY				
GEN.75900	*2*	**Electrical Grounding** There are records that all laboratory instruments and appliances are adequately grounded and checked for current leakage before initial use, after repair or modification, and when a problem is suspected.	NOTE: Exceptions to these requirements are as follows: 1. Devices protected by an approved system of double insulation or its equivalent. Such devices must be distinctively marked 2. Devices connected to wall receptacles or circuit breakers with ground-fault circuit interrupter (GCFI) protection built-in need not be checked for current leakage. ***GCFI interrupters must be utilized in areas where water may pose an added risk.*** 3. Equipment operating at 240 v must be checked for ground integrity only Verification of electrical safety is required whenever the electrical/electronic systems of a powered device has been removed or altered. Hospital laboratories may follow ground checks and current leakage checks as performed in patient locations. In addition, the U.S. Occupational Safety and Health Administration (OSHA) requires that power cords of portable electrical equipment be visually inspected for external defects whenever relocated. Grounding configurations may not be bypassed by, for example, an adapter that interrupts the continuity of the grounding. If manufacturer's recommendations for grounding are available, they must be followed.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) Section IX, Electrical Safety, Clinical Engineering/Facilities	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	http://facilities.jhmi.edu/Facilities(4/Facilitied/Engineering/Services.aspx#22
			CHEMICAL SAFETY				
GEN.76000	*2*	**Chemical Hygiene Plan** The laboratory has a Chemical Hygiene Plan (CHP) that defines the safety policies and procedures for all hazardous chemicals used in the laboratory.	**NOTE** 1: The laboratory director or designee must ensure that the laboratory has a written chemical hygiene plan (CHP) that defines the safety policies for all chemicals used in the laboratory. The plan must include evaluation of carcinogenic potential, reproductive toxicity, and acute toxicity. The plan must include specific handling requirements for all hazardous chemicals used in the laboratory. The purpose of the 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 laboratory director and supervisors 2. Designation of a qualified 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 laboratory. The product label, safety data sheet (SDS), or for chemicals purchased prior to June 1, 2015 with no appropriate SDS, records of investigation by the safety officer may be used for this evaluation 10. Specific handling requirements for all hazardous chemicals used in the laboratory	*✓Written evaluation of chemicals used in the laboratory for carcinogenic potential, reproductive toxicity and acute toxicity..* *✓Written procedure for chemical fume hood function verification AND* *✓Records of testing*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) Section X , and defaults to HSE 706 Chemical Hygiene Plan	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policy/156/10999/policy_10999.pdf?_=0.582017705762
GEN.76000 Cont.	*2*	**Chemical Hygiene Plan** The laboratory has a Chemical Hygiene Plan (CHP) that defines the safety procedures for all hazardous chemicals used in the laboratory.	NOTE 2: For laboratories subject to US regulations, chemicals that must be handled as potential carcinogens include those defined by OSHA as "select carcinogens." OSHA defines select carcinogens as any substance that is: : 1. Regulated as a carcinogen by OSHA, has been classified as "known to be carcinogenic" by the NTP, or listed as a group I carcinogen by the IARC 2. Has been classified as "reasonably anticipated to be carcinogenic" by the NTP or listed as a group 2A or 2B carcinogen by the IARC if it meets the toxicological criteria listed in the January 31, 1990 Fed Register, pages 3319-3320 OSHA also requires special containment procedures for substances that are reproductive toxins or are acutely hazardous. Authoritative sources include (but are not limited to) OSHA (Code of Federal Regulations. Title 29, Part 1910.1200 and, 1450); NIOSH (Registry of Toxic Effects of Chemical Substances); the National Toxicology Program; the International Agency for Research on Cancer, and Safety Data Sheets.				

GEN.76100	2	**Chemical Safety Document Access** Personnel have access to all of the following documents. 1. Current I Safety Data Sheets (formerly MSDS) and other references that list the details of hazards and the precautions for safe handling and storage 2. Chemical Hygiene Plan of the laboratory 3. Code of Federal Regulations, Title 29 part 1910.1450 and its appendices (laboratories subject to US regulations only)	NOTE: It is acceptable for SDS information to be electronically available to personnel, rather than in book format; there is no requirement for paper-based information. Indeed, electronic manuals have the advantage of more accurately reflecting current requirements. The central point is immediate availability to all personnel at all times.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL: Laboratory Safety manual section:X. GENERAL PRINCIPLES FOR SAFE HANDLING OF CHEMICAL HAZARDS. **// HSE Page to SDS (MSDS) link**	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.69663510877 5	https://www.hopkinsmedicine.org/hse/ds/index.html
GEN.76200	2	**Chemical Precautionary Labels** Precautionary labels are present on the containers of all hazardous chemicals, indicating type of hazard and what to do if accidental contact occurs.	NOTE: The laboratory may use signs, placards process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information otherwise required to be on a label. The written materials shall be readily accessible to the personnel in their work area throughout each work shift. It is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer. Existing labels on incoming containers of hazardous chemicals shall not be removed or defaced, unless the container is immediately marked with the required information. Additional requirements for the labeling and expiration date of chemicals used for the preanalytic and analytic testing process, such as reagent preparation, are included in the **Reagents section of the All Common Checklist**. Deficiencies cited relating to the labeling and expiration of chemicals are cited in the checklist section where the chemicals are used.		Chemical Labeling Policy LES005	https://hpo.johnshopkins.edu/hopkins/policies/68/9303/policy_9303.pdf?_=0.87003678101 1	
GEN.76300	2	**PPE And Hazardous Materials** 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.**		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) /HR003 Appearance and Image Standard	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.69663510877 5	https://hpo.johnshopkins.edu/hopkins/policies/68/6626/policy_6626.pdf?_=0.02160058659 73
GEN.76400	2	**Chemical Hazard Emergencies** Explicit instructions are posted, and appropriate supplies available, for the emergency treatment of chemical splashes and injuries and the control of chemical spills wherever major chemical hazards exist.	NOTE: Spill kits must be handled in accordance with ***manufacturer's*** instructions. **If no expiration date is assigned, the spill kit must indicate the date it was put into service and the laboratory director must periodically assess its usability.**		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.69663510877 5	
GEN.76500	2	**Flammable Storage** Supplies of flammable and combustible liquids are reasonable for the laboratory's needs, and are properly stored.	NOTE: 1. In each laboratory area, up to one gallon ***(3.7 L)*** of Class I, II and IIIA liquids may be stored outside of fire-resistant cabinets for each 100 ***ft² (9.2 m²)*** of space defined by fire-resistant walls/doors. Up to two gallons ***(7.5 L)*** of Class I, II, and IIIA liquids may be stored in safety cans and safety cabinets for each 100 ***ft² (9.2 m²)***. These amounts may be doubled if there is an automatic fire suppression system (e.g. sprinklers). For example: a ***1000 ft² (92.9 m²)*** laboratory defined by fire resistant walls/doors can store 10 gallons ***(37.8 L)*** outside a safety cabinet and 20 gallons ***(75.7 L)*** inside a safety cabinet and double those numbers if there is an automatic fire suppression system. 2. Safety cans should be used for bulk storage of flammable and combustible liquid (National Fire Protection Association classes I and II). Metal or DOT-approved plastic containers provide an intermediate level of hazard containment between glass and safety cans. One pint ***(0.4 L)*** of a highly volatile solvent such as isopentane, stored in glass has about the same ignitability risk as two gallons ***(7.5 L)*** stored in safety cans. Safety cans should be used instead of glass bottles if the purity required does not mandate glass storage				
GEN.76600	2	**Volatile Solvent Ventilation** Storage areas and/or rooms where volatile solvents are used are adequately ventilated.	NOTE: Areas where flammable liquids are used must be ventilated for protection of personnel, as well as fire prevention. Areas where flammable liquids are stored should be ventilated primarily for fire protection. Storage cabinets do not need to be vented, but if they are vented the duct system must be explosion proof.				
GEN.76700	2	**Acid/Base Storage** Supplies of concentrated acids and bases are stored safely.	NOTE: 1. Storage must be below eye level. Storage near the floor is recommended.. 2. Strong acids and bases **must** not be stored under sinks, where contamination by moisture may occur 3. Storage containers of acids and bases should be adequately separated to prevent a chemical reaction in the event of an accident/spill/leak. 4. Bottle carriers are used to transport all glass containers larger than 500 ml. that contain hazardous chemicals				
GEN.76720	2	**Formaldehyde and Xylene Safety** Formaldehyde and xylene vapor concentrations are monitored at the required intervals, and are maintained below all of the following maxima expressed as parts per million, in all areas of the laboratory where formaldehyde or xylene are used. **(see tab, labeled: FORMALDEHYDE and XYLENE)**	NOTE: Formaldehyde and xylene vapor concentrations must be monitored in all areas where these reagents are used (eg, surgical pathology, frozen section area, histology laboratory, manual/automated coverslipping areas, autopsy room, cytopathology, parasitology). Initial monitoring for formaldehyde involves the following: • Identifying allpersonnel who may be exposed at or above the action level (8-hr time-weighted exposure) or at or above the short term exposure limit (STEL) and • Accurately determining the exposure of each individual identified, either through measurement of exposure to each employee or through a representative sampling strategy If a representative sampling strategy is used instead of individual exposure monitoring the (sampling strategy must include measurement of sufficient exposures within each job classification for each work shift to correctly characterize and not underestimate the exposure of any employee within each exposure group. The results of the formaldehyde monitoring must be made available to personnel (individually in writing or posted in an accessible location) within 15 working days of receipt of results. If results are above the permissible exposure limit, personnel must be provided with a description of the corrective actions being taken to decrease exposure. Initial formaldehyde monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in **new or additional** exposure to formaldehyde .	*✓Written policy 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*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.69663510877 5	
GEN.76720 R		**Cont.** **Formaldehyde and Xylene Safety**	If exposure levels are at or above the action level or STEL, the laboratory must institute engineering controls and work practices to reduce and maintain employee exposures below these limits. If any personnel report signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the laboratory must promptly monitor the affected individual's exposure. Additional periodic formaldehyde monitoring is required if personnel are shown by initial monitoring to be exposed at or above the action level or at or above the STEL. This includes: • Repeat monitoring of the personnel at least every six months if the results are at or above the action level • Repeat monitoring of the personnel at least once a year under worst conditions if the last monitoring results are at or above the STEL • Periodic monitoring of personnel may be discontinued if results from two consecutive sampling periods taken at least seven days apart show that personnel exposure is below the action level and the STEL. Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene. Repeat monitoring should be considered when there is a change in production, equipment, process, personnel, or control measures likely to increase exposure levels.				
			COMPRESSED GASES				
GEN.76800	2	**Gas Cylinder Storage** Compressed gas cylinders are secured to prevent accidental falling and damage to the valve or regulator.			**Health Safety and Environment Manual Safety Policy: *Compress Gas Cylinders*** (HSE018)	https://hpo.johnshopkins.edu/hse/policies/156/10916/policy_10916.pdf?_=0.66047462870 8	
GEN.76900	2	**Flammable Gas Cylinders** Flammable-gas cylinders, if inside a health care facility, are stored properly.	NOTE: Proper storage practices include: 1 Storage in a separate, ventilated room or enclosure, 2 Cylinders are positioned well away from open flame or other heat sources, not in corridors and not within exhaust canopies.				
			RADIATION SAFETY				
GEN.77100	2	**Radioactive Material Handling - Specimens** There are specific policies and procedures for the safe handling of ***specimens*** 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 ***specimens*** containing radionuclides. The policies and procedures should distinguish between low radioactivity specimens such as sentinel lymphadenectomy and implant devices with higher radiation levels.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -= HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.69663510877 5	https://hpo.johnshopkins.edu/hse/?qvpt=section&sectionid=A1BB4CB94544CB912521C1D7E40A8DE5
		NOTE TO INSPECTOR: The following requirement applies to laboratories that do not perform anatomic pathology on-site, and for whom the Anatomic Pathology checklist is not used.					

GEN.77110	2	**Radiation Safety Manual** There is an up-to-date radiation safety manual that includes sections on decontamination and radioactive waste.	NOTE: A radiation safety manual providing procedures for the safe handling of radiation substances in both routine and emergency situations is required by the Nuclear Regulatory Commission (NRC). Requirements for laboratory safety in nuclear medicine can be found in several references.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77115	2	**Workspace Decontamination** Workbenches and sinks are decontaminated each day of use, and the effectiveness tested at least monthly	NOTE: If the laboratory uses only Iodine-125 either a wipe test or a portable scintillation probe can be used.	✓*Records of daily workbench/sink decontamination AND* ✓*Records of monthly effectiveness tests*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77120	2	**Radionuclides Handling** There are written policies regarding authorization or restriction of personnel handling radionuclides.	NOTE: These policies should be incorporated into the department's radiation safety manual		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77125	2	**Radionuclide Leak** There are written procedures for notification if a damaged or leaking radionuclide shipment is received.	NOTE: Procedures must include inspection, monitoring of shipments, and instructions for notification, if leakage or damage is noted in a radionuclide shipment.	✓*Records of inspections and notifications*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77130	2	**Radionuclide Storage** Radionuclide storage and decay areas are properly shielded, if required for specific isotopic materials.	NOTE: Radionuclide storage and decay areas must be properly shielded, if required for specific isotopic materials, to avoid excessive exposure to personnel and interference with counting procedures.	✓*Written procedure defining shielding requirements for radionuclide storage an decay areas*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77135	2	**Radiation Surveys** There are regular radiation area surveys and wipe tests, with records maintained.	NOTE: Routine radiation surveys and wipe tests to determine exposure rates and detect contamination must be performed and recorded at defined frequency.	✓*Written procedure defining frequency of radiation survey and wipe tests to determine exposure rates and detect contamination*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77140	1	**Radioactive Material Sign** All areas or rooms where radioactive materials are being used or stored are posted to indicate the presence of radioactive materials.	NOTE: For US laboratories, all areas or rooms where radioactive materials are being used or stored must be posted to indicate the presence of radioactive materials, consistent with 10CFR20, Appendix C.		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77145	2	**Radionuclide Training** Personnel receive training in decontamination routines and in the safe handling and proper disposal of radionuclides (wastes, syringes, needles, and sponges) with records ***retained***.		✓*Records of radionuclide training in personnel file*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77150	2	**Radioactive Waste** Radioactive waste is stored separately, under required conditions, and appropriately discarded, with records ***retained***.	NOTE: Records of the radioactive trash disposal must be ***retained***. For US laboratories, NRC regulations specify that separate areas be established for the receipt of radioactive waste and that these areas be properly shielded to reduce radiation levels below those maximum permissible limits specified in 10CFR20.	✓*Written procedure defining criteria for proper storage and disposal of radioactive waste*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
GEN.77155	2	**Safety Committee Representation** There are records indicating that a laboratory representative is a member of and/or attends institutional radiation safety committee meetings regularly.	NOTE: Independent laboratories must have a radiation safety officer who fulfills the functions of an institutional radiation safety committee	✓*Records of laboratory participation in institutional Safety Committee meeting OR participationin other appropriate group responsible for radiation safety*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004)	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/?event=section&sectionid=A1884C894544CB912521C107E40ABDE5
			ENVIRONMENTAL SAFETY				
GEN.77200	2	**Ergonomics** There is a written ergonomics program to prevent musculoskeletal disorders (MSDs) in the workplace through prevention and engineering controls.	NOTE: The program may include training of personnel about risk factors, identifying physical work activities or conditions of the job commonly associated with work-related MSDs, and recommendations for eliminating MSD hazards. Laboratory activity, workplace and equipment (e.g. chairs, laboratory workstations, computer keyboards, and displays) should be designed to reduce the risks of ergonomic distress disorders and accidents	✓*Records of ergonomic evaluation including recommendations for eliminating MSD hazards and appropriate corrective action based on assessment findings*	Health Safety and Environment Manual Safety Policy: Ergonomics (HS0049)	https://hpo.johnshopkins.edu/hse/policies/156/19326/policy_19326.pdf?_=0.041560640834	https://hpo.johnshopkins.edu/hse/policies/156/19326/policy_19326.pdf?_=0.078488566014
GEN.77300	2	**Excessive Noise** The laboratory has a policy to protect personnel from excessive noise levels.	NOTE: The laboratory should provide protection against the effects of noise exposure when sound levels equal or exceed an 8-hour time-weighted average sound level of 85 decibels. The laboratory should monitor noise exposure if there is an indication that excessive noise levels are present (for example, when noise levels exceed 85 decibels, people have to shout to be heard)		Johns Hopkins Guidance Documents- Exposure to Excessive Noise HSEGD04	https://hpo.johnshopkins.edu/hse/policies/156/11030/policy_11030.pdf?_=0.934024297373	https://hpo.johnshopkins.edu/hse/policies/156/11030/policy_11030.pdf?_=0.651188079278
GEN.77400	2	**Emergency Eyewash** The laboratory has adequate plumbed or self-contained emergency eyewash facilities in every area where there exposure to the eye from corrosive chemicals, as defined by the laboratory's chemical hygiene plan, may occur. Testing records are ***retained***.	NOTE The chemical hygiene plan must include provisions for the safe handling of all chemicals used in the laboratory. Chemicals with corrosive properties (refer to the safety data sheet) that may potentially be exposed to the eye must be handled in a work area with appropriate eyewash facilities. A risk-based approach may be used to determine appropriate eyewash facility placement. Immediate and prolonged (15 minutes) flushing is generally necessary for corrosive/alkali agents. If the water is not at an appropriate temperature, it may add to the injury. The eyewash facilities must meet the following criteria: For all laboratories: 1. No greater than 10 seconds travel distance from areas in the laboratory where hazardous 2. Signage for location of eyewash 3. Unobstructed path with unlocked doors opening in the direction of the eyewash. 4. Tepid fluid temperature.(Water temperature should be between 15°C and 37°C (60°F and 100°F). Actual temperature recording is not required.) 5. Plumbed systems are activated weekly		DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) **// IH safety manual** Emergency Equipment: Eye Wash, Drenching Hose and Shower Equipment HSE 037	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policies/156/10941/policy_10941.pdf?_=0.627984389017
GEN.77400	2	**Emergency Eyewash cont.**	6. Self-contained units are visually examined weekly In addition, the following are required for laboratories subject to US OSHA regulation and are recommended for all laboratories: 7. Capable of delivering 1.5 L per minute for 15 minutes 8. Flow is provided to both eyes simultaneously 9. Nozzles or covers to protect from airborne contaminants 10. Hands-free flow once activated 11. Plumbed systems are protected from unauthorized shut off For self-contained eyewash facilities, the manufacturer's specifications should be available for review by an inspector. The availability of disposable eyewash bottles in the work area does not replace the need for an eyewash facility in areas at risk for eye exposure from corrosive chemicals.				
			OTHER HAZARDS				
GEN.77500	2	**Liquid Nitrogen *and Dry Ice*** Adequate policies, procedures, and practices are in place for the use of liquid nitrogen ***(LN2) and dry ice.***	NOTE: Practices for the safe handling of liquid nitrogen ***and dry ice*** include: 1. The mandatory use of appropriate gloves, shielding of all skin and the use of a face shield ***or safety goggles*** when decanting or entering an open container of ***LN2*** ***2. The mandatory use of insulated gloves, dry ice tongs or scoop, and safety goggles/glasses when handling dry ice. Do not use or store dry ice or LN2 in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. An LN2 or CO2 leak in such an area could cause an oxygen-deficient atmosphere.*** ***3.*** Storage and use of all containers of ***LN2 and dry ice*** only in well-ventilated areas ***4.*** Availability of a Safety Data Sheet ***5.*** ***Training on the safe handling of LN2 and dry ice*** ***6. Signage displayed in areas where LN2 is used and/or stored.*** ***7. Plan for immediate treatment for individuals overcome by toxic or oxygen-displacing fumes***		THE JOHNS HOPKINS UNIVERSITY / THE JOHNS HOPKINS HOSPITAL (HSE) CRYOGENIC LIQUIDS AND DRY ICE	https://hpo.johnshopkins.edu/hse/policies/156/10937/policy_10937.pdf?_=0.781019583514	
GEN.77550	2	***Liquid NitrogenSafety*** The laboratory has identified areas where liquid nitrogen (LN2) is used, and/or stored, and there are appropriately mounted oxygen sensors with a low oxygen alarm in all areas where there is an asphyxiation risk..	***NOTE:*** At room temperature liquid nitrogen is converted to nitrogen gas, at an expansion ratio of approximately 1-700 (1 L LN2/700 L nitrogen gas). This creates a potential occupational hazard for an oxygen deficient atmosphere. The Occupational Safety and Health Administration (OSHA) states that a hazardous atmosphere may include one where the oxygen concentration is below 19.5% . The risk of asphyxiation with the use of LN2 is dependent upon the amount and rate of nitrogen gas release, the proximity of personnel, and the ventilation in the area. The laboratory must assess the use of LN2 and determine the risk in the event of a leak or spill of all of the LN2 used in each area and assess the risk of asphyxiation. Functioning oxygen sensors should be in place in all areas where there is a risk of asphyxiation including: confined spaces (eg, cold rooms, closets), poorly ventilated areas, or areas with significant quantities of LN2. For example, on vaporization, one liter of LN2 will fill 24.6 cu ft of space.		THE JOHNS HOPKINS UNIVERSITY / THE JOHNS HOPKINS HOSPITAL (HSE) CRYOGENIC LIQUIDS AND DRY ICE	https://hpo.johnshopkins.edu/hse/policies/156/10937/policy_10937.pdf?_=0.781019583514	
cont. GEN.77550	2	***cont.*** ***Liquid Nitrogen Safety***	Use of small volumes of LN2 (eg, ≤1 liter) by trained personnel in well ventilated areas may not require oxygen sensors. The assessment and the determination that these areas do not require oxygen sensors must be recorded by the laboratory. Appropriate placement of oxygen sensors is at typical breathing height close to where liquid nitrogen is used and where a leak would most likely occur. A low oxygen alarm must be installed along with the oxygen sensor to alert persons in the area of a hazardous condition. Oxygen monitoring devices need to be maintained and calibrated following manufacturer instructions. Device display/readout should be visually checked following a defined schedule to ensure proper operation.				

GEN.77575	*2*	***Evacuation /Clean -up Plan- Biorepository Only*** The biorepository has a plan for evacuation and clean-up in the event of an LN2 or liquid CO2 spill from a bulk source			THE JOHNS HOPKINS UNIVERSITY / THE JOHNS HOPKINS HOSPITAL (HSE) CRYOGENIC LIQUIDS AND DRY ICE	https://hpo.johnshopkins.edu/hse/policies/156/10937/policy_10937.pdf?_=0.78101958514	
GEN.77600	*2*	**UV Light Exposure** 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. Whenever 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	*✓Warning signage on source equipment AND* *✓Suitable PPE available, as required*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) JHH Safety policy	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	
GEN.77700	*2*	**Latex Allergy** The laboratory has a written program to protect personnel and patients from allergic reactions from exposures to natural rubber latex in gloves and other products.	NOTE: The latex program should address at least the following elements: 1. Selection of products and implementation of work practices that reduce the risk of allergic reactions. If latex gloves are used, the employer should provide reduced protein, powder-free gloves to protect personnel from infectious materials 2. Provision of education programs and training materials about latex allergy 3. Evaluation of current prevention and control strategies for personnel whenever there is a new latex allergy diagnosis	*✓Records of personnel education/training on latex allergies AND* *✓Records of evaluation of the plan, when appropriate*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Latex Allergy Policy and Procedure for Laboratory Staff (LES002)	https://hpo.johnshopkins.edu/hopkins/policies/68/4349/policy_4349.pdf?_=0.27881890842	
			WASTE DISPOSAL				
GEN.77800	*2*	**Hazardous Chemical Waste Disposal** Written policies and procedures are adequate for hazardous chemical waste disposal.	NOTE: **1.** The laboratory is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition. **2.** The method for the disposal of all solid and liquid wastes is in compliance with ***national, federal***, state ***(or provincial), local laws and*** regulations. (Whether or not laboratory management is responsible for waste disposal, the laboratory should have documentation that the facility is in compliance with all applicable regulations. Prevailing local, state and federal (EPA) regulations should be reviewed by the laboratory director, safety officer or hospital engineer to ensure that the laboratory is in compliance with regulations.)	*✓Records of review of regulations for compliance*	DEPARTMENT OF PATHOLOGY GENERAL POLICY MANUAL-A-Personnel -– HPO;Safety and Facilities; Johns Hopkins Medical Laboratories Safety Manual (LES004) , records held at HSE703	https://hpo.johnshopkins.edu/hopkins/policies/68/6687/policy_6687.pdf?_=0.696635108775	https://hpo.johnshopkins.edu/hse/policies/156/10996/policy_10996.pdf?_=0.881431908975
GEN.77825	*2*	***Hazardous Waste Registration and Regulations*** Laboratories that generate hazardous wastes are registered with the Environmental Protection Agency (EPA) and/or appropriate national, federal, state (or provincial), and local governmental agencies, as applicable, and comply with applicable regulations based on the amount of wastes generated.	NOTE: For laboratories subject to US regulations, requirements for registration and record keeping vary based on the amounts of hazardous waste generated and by the state in which the laboratory is located. Laboratories that are categorized as "very small quantity" generators do not require registration in most states. "Small quantity" generators and "large quantity" generators are usually required to register with the EPA, even if the laboratory contracts with a service for waste disposal. Information on defining hazardous wastes, waste generator categories, and variations between states can be found at www.epa.gov. Links to hazardous waste programs and specific state agencies can be found at *https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies* . Laboratories that are part of a larger facility that generates hazardous waste may register with the facility and maintain facility records. Laboratories that are not subject to US regulations must follow applicable national, state or provincial, and local laws and regulations for hazardous wastes.	*✓EPA registration, if applicable AND* *✓Records of hazardous waste management, if applicable*	Registration of Hazardous Chemicals-HSE 704	https://hpo.johnshopkins.edu/hse/policies/156/10997/policy_10997.pdf?_=0.998455276877	
GEN.77900	*2*	**Biohazard Disposal Containers** All infectious wastes (e.g. glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded into "biohazard"- labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal.	NOTE: All infectious wastes must be incinerated or appropriately decontaminated before being sent to a sanitary landfill. Stool and urine waste may be discarded into the sanitary sewerage system.		Laboratory waste disposal- HSE 805	https://hpo.johnshopkins.edu/hse/policies/156/11005/policy_11005.pdf?_=0.1295636019 76	
GEN.78000	*2*	**Sharps Disposal** Sterile syringes, needles, lancets, or other blood-letting devices ("sharps") that are capable of transmitting infection are used once only, and all waste sharps are discarded in puncture-resistant containers that are easily accessible, located in areas where needles are commonly used, and properly labeled to warn handlers of the potential hazard.	NOTE: Shearing or breaking of contaminated sharps is prohibited. Bending, recapping, or removing contaminated needles is prohibited as a general practice. Needles are expected to be used and immediately discarded, un-recapped, into accessible sharps containers.		Laboratory waste disposal- HSE 805		https://hpo.johnshopkins.edu/hse/policies/156/11005/policy_11005.pdf?_=0.145546808367

2020 CHECKLIST EDITION CHANGES

New Checklist requirements		**Effective date**
GEN	20318	6/4/2020
GEN	20430	6/4/2020
GEN	74050	6/4/2020
Revised Checklist Requirement		
GEN	13806	6/4/2020
GEN	20100	6/4/2020
GEN	20208	6/4/2020
GEN	20310	6/4/2020
GEN	20316	6/4/2020
GEN	20320	6/4/2020
GEN	20325	6/4/2020
GEN	20326	6/4/2020
GEN	20327	6/4/2020
GEN	20330	6/4/2020
GEN	20374	6/4/2020
GEN	20377	6/4/2020
GEN	26791	6/4/2020
GEN	41077	6/4/2020
GEN	41096	6/4/2020
GEN	43022	6/4/2020
GEN	43875	6/4/2020
GEN	48500	6/4/2020
GEN	74000	6/4/2020
GEN	74100	6/4/2020
GEN	74250	6/4/2020
GEN	74400	6/4/2020
GEN	74500	6/4/2020
GEN	74600	6/4/2020
GEN	74700	6/4/2020
GEN	74900	6/4/2020
GEN	78275	6/4/2020

Retention Table ###

Type of Record/Material	Retention Period
Specimen requisitions (including the patient chart or medical record if used as the requisition)	2 years
Accession records	
Quality management records	
Test method validation//verification records	Length of time the test is in use, plus 2 additional years
Proficiency testing records	2 years
Policies and procedures	At least 2 years following discontinuance
Quality control records	2 years
Individualized Quality Control Plan (IQCP), including risk assessment and supporting data, and approval of quality control plan ....Ongoing quality assessment data.	Length of time the test is in use, plus 2 additional years .... 2 years
Instrument /equipmentmaintenance* and function check records (including temperature charts)	2 years
Chain -of- custody collection , receipt, accessioning, and handling records	2 years (or longeras applicable)
Personnel Records	**Retention Period**
Competency assessment records	2 years
Training records	
Patient Specimens (stored under appropriate conditions)	**Retention Period**
Serum, and plasma	48 hours; exceptions may be made at the discretion of the laboratory director ** At the discretion of the laboratory director (see HEM.36940)
Citrated plasma,	48 hours
CSF, and body fluids (except urine)	**At the discretion of the laboratory director**
Whole blood specimens, including blood gas specimens	
Urine	24 hours; exceptions may be made at the discretion of the laboratory director.
Clinical Pathology Slides	**Retention Period**
Blood Films	7 days
Permanently stained body fluid slides	
Permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles)	
Testing Records	**Retention Period**
Instrument printouts **(not interfaced with the laboratory computer system)**and worksheets ***	2 years
Patient test results and reports, including original and corrected reports, and referral laboratory reports	

Direct-to-consumer testing results, including reference intervals	10 years
Laboratory Computer Services	**Retention Period**
Computer system validation records	2 years beyond the life of the system
Records of changes to software, the test library, and major functions of laboratory information systems	
Ongoing computer system checks (eg. calculation verification)	2 years
* Laboratories may wish to retain instrument maintenance records for longer than the two-year requirement (eg, for the life of the instrument), to facilitate trouble-shooting.	
** Longer storage requirements may be necessary for patients admitted for suspected drug overdoses. The preferred specimens for most toxicological methods include a urine specimen and a gray top tube with the anti-coagulants potassium oxalate and sodium fluoride collected soon after hospital admission; however, any serum specimen from admission is acceptable. The CAP suggests (but does not require) retaining such specimens for 30 days after presentation to the hospital or at least 48 hours after hospital discharge or death. Specimens collected post-mortem may be inadequate to determine the cause of death if the patient was hospitalized or underwent resuscitative efforts.	

	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
Xylene	100		150