Every patient deserves the GOLD STANDARD ...

Laboratory General Checklist

CAP Accreditation Program
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# Laboratory General Checklist

## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUMMARY OF CHANGES</td>
<td>6</td>
</tr>
<tr>
<td>UNDERSTANDING THE 2010 CAP ACCREDITATION CHECKLIST COMPONENTS</td>
<td>9</td>
</tr>
<tr>
<td>HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES</td>
<td>10</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>11</td>
</tr>
<tr>
<td>QUALITY MANAGEMENT</td>
<td>11</td>
</tr>
<tr>
<td>SPECIMEN COLLECTION, DATA HANDLING, AND REPORTING</td>
<td>20</td>
</tr>
<tr>
<td>COLLECTION MANUAL AND OTHER DOCUMENTATION</td>
<td>20</td>
</tr>
<tr>
<td>SPECIMEN COLLECTION</td>
<td>22</td>
</tr>
<tr>
<td>TRANSPORT SERVICES</td>
<td>26</td>
</tr>
<tr>
<td>REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/ASSESSMENT</td>
<td>28</td>
</tr>
<tr>
<td>REPORTING OF RESULTS</td>
<td>32</td>
</tr>
<tr>
<td>DIRECT- TO- CONSUMER TESTING</td>
<td>39</td>
</tr>
<tr>
<td>QUALITY OF WATER AND GLASSWARE WASHING</td>
<td>40</td>
</tr>
<tr>
<td>LABORATORY COMPUTER SERVICES</td>
<td>41</td>
</tr>
<tr>
<td>COMPUTER FACILITY</td>
<td>42</td>
</tr>
<tr>
<td>LIS/COMPUTER PROCEDURE MANUAL</td>
<td>43</td>
</tr>
<tr>
<td>HARDWARE AND SOFTWARE</td>
<td>44</td>
</tr>
<tr>
<td>SYSTEM MAINTENANCE</td>
<td>45</td>
</tr>
<tr>
<td>SYSTEM SECURITY</td>
<td>46</td>
</tr>
<tr>
<td>PATIENT DATA</td>
<td>47</td>
</tr>
<tr>
<td>AUTOVERIFICATION</td>
<td>49</td>
</tr>
<tr>
<td>DATA RETRIEVAL AND PRESERVATION</td>
<td>50</td>
</tr>
<tr>
<td>INTERFACES</td>
<td>51</td>
</tr>
<tr>
<td>TELEPATHOLOGY</td>
<td>53</td>
</tr>
<tr>
<td>PERSONNEL</td>
<td>55</td>
</tr>
<tr>
<td>TECHNICAL SUPERVISORS</td>
<td>55</td>
</tr>
<tr>
<td>GENERAL SUPERVISORS</td>
<td>56</td>
</tr>
<tr>
<td>ALL PERSONNEL</td>
<td>57</td>
</tr>
<tr>
<td>PHYSICAL FACILITIES</td>
<td>60</td>
</tr>
<tr>
<td>SPACE</td>
<td>60</td>
</tr>
<tr>
<td>ENVIRONMENT</td>
<td>61</td>
</tr>
<tr>
<td>COMMUNICATIONS</td>
<td>61</td>
</tr>
<tr>
<td>INVENTORY AND STORAGE OF SUPPLIES</td>
<td>62</td>
</tr>
<tr>
<td>POWER</td>
<td>62</td>
</tr>
<tr>
<td>LABORATORY SAFETY</td>
<td>62</td>
</tr>
<tr>
<td>SAFETY POLICIES AND RECORDS</td>
<td>63</td>
</tr>
<tr>
<td>BLOODBORNE PATHOGENS</td>
<td>65</td>
</tr>
<tr>
<td>OTHER INFECTIOUS HAZARDS</td>
<td>68</td>
</tr>
<tr>
<td>FIRE PREVENTION AND PROTECTION</td>
<td>69</td>
</tr>
<tr>
<td>ELECTRICAL SAFETY</td>
<td>72</td>
</tr>
<tr>
<td>CHEMICAL SAFETY</td>
<td>72</td>
</tr>
<tr>
<td>COMPRESSED GASES</td>
<td>75</td>
</tr>
</tbody>
</table>
RADIATION SAFETY ................................................................. 76
ENVIRONMENTAL SAFETY ......................................................... 77
OTHER HAZARDS ........................................................................ 78
WASTE DISPOSAL ....................................................................... 80
SUMMARY OF CHECKLIST EDITION CHANGES
Laboratory General Checklist
07/11/2011 Edition

The following requirements have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the requirements included may not appear in the customized checklist. Such requirements are not applicable to the testing performed by the laboratory.

Note: For revised checklist requirements, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.

### NEW Checklist Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEN.20340</td>
<td>07/11/2011</td>
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<tr>
<td>GEN.41077</td>
<td>06/17/2010</td>
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<tr>
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### REVISED Checklist Requirements

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<thead>
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<td>07/11/2011</td>
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<td>07/11/2011</td>
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<td>07/11/2011</td>
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<td>07/11/2011</td>
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</table>
Laboratory General Checklist
07.11.2011

DELETED Checklist Requirements

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</thead>
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<td>07/10/2011</td>
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<td>07/10/2011</td>
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<tr>
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<tr>
<td>GEN.40550</td>
<td>07/10/2011</td>
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<tr>
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<td>07/10/2011</td>
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<td>GEN.41250</td>
<td>07/10/2011</td>
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<tr>
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<td>07/10/2011</td>
</tr>
<tr>
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<td>07/10/2011</td>
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<td>07/10/2011</td>
</tr>
<tr>
<td>GEN.41370</td>
<td>07/10/2011</td>
</tr>
<tr>
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<td>06/16/2010</td>
</tr>
<tr>
<td>GEN.41495</td>
<td>07/10/2011</td>
</tr>
<tr>
<td>GEN.41550</td>
<td>07/10/2011</td>
</tr>
<tr>
<td>GEN.41700</td>
<td>07/10/2011</td>
</tr>
<tr>
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<td>07/10/2011</td>
</tr>
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<td>GEN.41850</td>
<td>07/10/2011</td>
</tr>
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<td>GEN.42005</td>
<td>07/10/2011</td>
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<td>GEN.42020</td>
<td>07/10/2011</td>
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<td>07/10/2011</td>
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<tr>
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<td>07/10/2011</td>
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<td>07/10/2011</td>
</tr>
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<td>GEN.42140</td>
<td>07/10/2011</td>
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<tr>
<td>GEN.42160</td>
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<td>07/10/2011</td>
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<td>GEN.42163</td>
<td>07/10/2011</td>
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<td>GEN.42457</td>
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</tr>
<tr>
<td>GEN.42850</td>
<td>07/10/2011</td>
</tr>
</tbody>
</table>
UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

To provide laboratories with a better means to engage in and meet their accreditation requirements, the CAP has enhanced the checklist content and updated its design. New components containing additional information for both the laboratory and inspectors include Subject Headers, Declarative Statements and Evidence of Compliance. See below for a definition of each new feature as an example of how they appear in the checklists.

Using Evidence of Compliance (EOC)

This component, which appears with several checklist requirements, is intended to:

1. Assist a laboratory in preparing for an inspection and managing ongoing compliance
2. Drive consistent understanding of requirements between the laboratory and the inspector
3. Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.)

In addition to the Evidence of Compliance listed in the checklist, other types of documentation may be acceptable. Whenever a policy/procedure/process is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies/procedures/processes covered in the CAP checklists must be documented. A separate policy is not needed for each item listed in EOC as it may be referenced in an overarching policy.
**HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES**
*(Read, Observe, Ask, Discover)*

CAP has streamlined the inspection approach used during onsite inspections and is now offering guidance to inspectors by providing assessment techniques to facilitate a more efficient, consistent, and effective inspection process. Specific inspector instructions are listed at the beginning of a grouping of related requirements.

Rather than reviewing each individual requirement, CAP inspectors are encouraged to focus on the Inspector Instructions for a grouping of related requirements. Once an area of concern has been identified through "Read," "Observe," "Ask," "Discover," or a combination thereof, inspectors are encouraged to "drill down" to more specific requirements, when necessary and review more details outlined in the Evidence of Compliance statements. If a requirement is non-compliant, circle the requirement number to later list on the Inspector Summation Report. Inspectors may also make notes in the margins of the checklist document.

Inspector Instructions and Icons used to evaluate a laboratory's performance now appear in several areas throughout the Inspector Checklists. Please note that all four R.O.A.D elements are not always applicable for each grouping, or sections of related requirements.

**Inspector Instructions:**

| READ | Review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff. (Example of the complimentary inspector instructions for Quality Management/Quality Control General Issues section appearing across checklists):
|---|---
| ● Sampling of QM/QC policies and procedures  
● Incident/error log and corrective action |
| OBSERVE | Laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures. (Example)
| ● Observe the settings/QC range limits established in the laboratory LIS/HIS to ensure that the laboratory's stated ranges are accurately reflected |
| ASK | Open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process. (Example)
| ● As a staff member, what is your involvement with quality management?  
● How do you detect and correct laboratory errors? |
| DISCOVER | A tool that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously. (Example)
| ● Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action |
INTRODUCTION

The Laboratory General Checklist applies to all sections of the laboratory. An inspection of a laboratory section, or detent will include the discipline-specific checklist(s) (e.g. Anatomic Pathology), the Laboratory General Checklist, and the All Common Checklist (COM).

In response to the ongoing request to reduce the redundancy within the Accreditation Checklists, the CAP accreditation program has created the All Common Checklist.

The purpose of the All Common Checklist is to group together those requirements that were redundant in Laboratory General and the discipline-specific checklists. Therefore, the CAP centralized all requirements regarding: proficiency testing, procedure manuals, test method validation, and critical results into one checklist, the COM checklist.

Note for non-US laboratories: Checklist requirements apply to non-US laboratories unless the checklist items contain a specific disclaimer of exclusion.

QUALITY MANAGEMENT

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

Although effective organization of the laboratory and appropriate delegation of duties are part of quality management, these areas are addressed in the Team Leader checklist. Quality management requirements pertaining to individual laboratory sections are addressed in the applicable laboratory section checklist.

Inspector Instructions:

- Sampling of QM/QC policies and procedures
- Policy for communication of employee concerns
- Sampling of quality indicators with follow-up actions when targets are not achieved
- Annual appraisal of effectiveness of the QM Program
- Document control policy
- Record/specimen retention policy
- Error, complaint and incident logs with corrective/preventative actions
- Device-related adverse patient event procedure and records of reporting (if applicable)
- Results of the laboratory's self-evaluation and correction of deficiencies
- Sampling of records of manufacturer's recalls and follow-up documentation
- CAP sign regarding the reporting of quality concerns
- How is the laboratory's QM performance communicated to other hospital departments?
Laboratory General Checklist

**REVISIONS** 07/11/2011
GEN.13806 Documented QM Plan

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

**NOTE:** There must be a document that describes the overall QM program. The document need not be detailed, but should spell out the objectives and essential elements of the QM program. The QM plan may be based upon some reference resource such as CLSI HS01-A2, GP22-A2, or GP26-A3; the ISO 9000 series or ISO 15189; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design. If the laboratory is part of a larger organization, the laboratory QM program is coordinated with the organization's QM plan.

REFERENCES

**REVISIONS** 07/11/2011
GEN.16902 QM Implementation

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

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

**Evidence of Compliance:**

✓ Evidence that the plan has been implemented as designed requires all of the following:
  • quality measurements/assessments specified in the plan are being substantially carried out;
  • there is evidence of active review of quality measurements;
  • if target performance levels are specified in the plan and the targets are not being met,
there is documented follow-up action;

- any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay documented; **AND**
- any communication of information that is required by the plan have taken place

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

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

NOTE: The QM plan 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 reference laboratory services.

**REVISED**  
07/11/2011

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

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

NOTE: There must be an organized program for documentation of problems involving the laboratory that are identified internally, as well as those identified through outside sources such as complaints from patients, physicians or nurses. The program must be implemented in all sections of the laboratory, and on all shifts. Any problem that could potentially interfere with patient care or safety must be addressed. Clinical, rather than business/management issues, should be emphasized. The laboratory must document investigation and resolution of these problems. Laboratories must perform root cause analysis of any unexpected event involving death or serious physical or psychological injury, or risk thereof (including “near misses” and sentinel events). Laboratories must be able to demonstrate appropriate risk-reduction activities based on such root cause analyses.

REFERENCES

2) Spath PL. How to conduct a thorough sentinel event investigation. J Healthcare Risk Mgmt. 1998;18(4):5-6

**REVISED**  
07/11/2011

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

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

NOTE: Key indicators are those that reflect activities critical to patient outcome, that affect a large proportion of the laboratory’s patients, or that have been problematic in the past. The laboratory must document that the selected indicators are regularly compared against a benchmark, where available and applicable. The benchmark may be a practice guideline, CAP Q-PROBES data, or the laboratory's own experience. New programs or services should be measured to evaluate their impact on laboratory service. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor a single indicator; larger laboratories should monitor multiple aspects of the scope of care commensurate with their scope of service. (However, there is no requirement that an indicator(s) be assessed in every section of the laboratory during every calendar year.)
Examples of key indicators include, but are not limited to the following. (Indicators related to CAP patient safety goals include numbers 1, 4, 7, 8 and 9.)

1. **Patient/Specimen Identification.** May be any of the following: percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors.
2. **Test Order Accuracy.** Percent of test orders correctly entered into a laboratory computer.
3. **Stat Test Turnaround Time.** May be collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a “stat” priority. May be confined to the Emergency Department or intensive care unit if a suitable reference database is available. Laboratories may monitor mean or median turnaround time or the percent of specimens with turnaround time that falls within an established limit.
4. **Critical Value Reporting.** Percent of critical results with documentation 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.
5. **Customer Satisfaction.** Must use a standardized satisfaction survey tool with a reference database of physician or nurse respondents.
6. **Specimen Acceptability.** Percent of general hematology and/or chemistry specimens accepted for testing.
7. **Corrected Reports – General Laboratory.** Percent of reports that are corrected.
8. **Corrected Reports – Anatomic Pathology.** Percent of reports that are corrected.
9. **Surgical Pathology/Cytology Specimen Labeling.** Percent of requisitions or specimen containers with one or more errors of pre-defined type.
10. **Blood Component Wastage.** Percentage 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 reissu.
11. **Blood Culture Contamination.** Percent of blood cultures that grow bacteria that are highly likely to represent contaminants.

While there is no requirement that the specific key quality indicators listed above be monitored, these indicators have been field-tested and shown to be measurable in a consistent manner, to demonstrate variability from laboratory-to-laboratory, and to be important to clinicians and to patient care. For the above indicators, performance should be compared with multi-institutional performance surveys that have been conducted within ten years of the laboratory’s most recent measurement, where such surveys are available (see references below). Action plans should be developed for any indicator in which laboratory performance falls below the 25th percentile (i.e., 75% or more of the other laboratories in the study perform better). Use of the indicators listed above does not require enrollment in any quality monitoring product.

**REFERENCES**

1) Clinical Laboratory Improvement Amendments 42 CFR § 493.1701
**GEN.20325  Employee Quality Communication**  
**Phase II**

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

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

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

**GEN.20330  CAP Sign**  
**Phase II**

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

**NOTE:** The laboratory must prominently post the official CAP sign regarding the reporting of quality concerns to CAP.

While personnel should report concerns to laboratory management, the laboratory must ensure that all personnel know that they may communicate with CAP directly if they have a concern not addressed by laboratory management, and that 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 CAP or other regulatory organization regarding laboratory quality or safety.

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

Official CAP signs may be obtained by calling 800-323-4040 option 1#.

**GEN.20335  Customer Satisfaction**  
**Phase II**

Referring physicians'/clients' or patients' satisfaction with laboratory service was measured within the past 2 years.

**NOTE:** For patients, satisfaction with the phlebotomy service may be measured.

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

**REFERENCES**

**NEW**  
**07/11/2011**

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

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

**NOTE:** Notifications may take the form of product recalls, market withdrawals, or software patches and upgrades. The laboratory should take action on those that have the potential to affect testing results or laboratory services.
Evidence of Compliance:
✓ Records of manufacturer's recalls received **AND**
✓ Follow-up documentation

GEN.20371  Adverse Patient Event Reporting

**Phase I**

The laboratory has a procedure for reporting device-related adverse patient events, as required by 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 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 FDA. Reports must be submitted on 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-US laboratories.

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, precision, etc.) 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. Further details are available at [http://www.fda.gov/cdrh/mdruf.pdf](http://www.fda.gov/cdrh/mdruf.pdf). Laboratories that are part of a larger organization (e.g. hospital laboratories) should document participation in the overall institutional MDR process.

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 (or an electronic equivalent) by January 1 of each year. The laboratory or institution must keep records of MDR reports for 2 years.


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

Evidence of Compliance:
✓ Records of MDR reports for reportable events, if applicable
State/Local Regulations

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

NOTE: Applicable state and local requirements may include but are not limited to the following areas: handling radioactive materials, shipping infectious or diagnostic materials, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results, and donation of blood. The checklists contain specific requirements on these areas.

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

REFERENCES

Document Control

The laboratory has a document control system.

NOTE: Document control requirements apply to all policies, procedures and forms (including quality management documents) for all processes and activities that are subject to CAP accreditation. The laboratory must have a document management or control system to assure that: 1, all copies of policies and procedures are current; 2, personnel have read the policies/procedures relevant to their job activities; 3, all policies/procedures have been authorized by the laboratory director, before implementation; 4, policies and procedures are reviewed at least biennially by the laboratory director or designee; 5, discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine). It is recommended that the laboratory maintain a control log listing all current policies and procedures and the locations of copies (including derivative documents such as card files and summary charts). The control log may contain other information as appropriate, such as dates when policies/procedures were placed in service, schedule of review, identity of reviewer(s), and dates when policies/procedures were discontinued/superseded.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures must be subjected to proper document control. Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

Additional requirements regarding procedure manuals are found in section-specific checklists, and in this checklist in the Collection Manual, Computer Services and Safety sections.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI); Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition. CLSI document GP2-A5 (ISBN 1-56238-600-X); Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite
Laboratory records and materials are retained for an appropriate time.

NOTE: The following records must be retained for at least 2 years: specimen requisitions (including the patient chart or medical record only if used as the requisition), patient test results and reports, instrument printouts, accession records, quality control records, instrument maintenance records, proficiency testing records, and quality management records. Specimens of serum, heparinized plasma, EDTA plasma, CSF, and body fluids (except urine) should be retained for 48 hours. (The 48 hour retention requirement does not apply to whole blood samples; for example, samples collected for blood gas testing.) Urine specimens should be retained for 24 hours; exceptions may be made at the discretion of the laboratory director. Blood films, permanently stained body fluid slides, and permanently stained microbiology slides prepared from clinical specimens (including blood culture bottles) should be retained for 7 days.

Specimens must be kept under appropriate storage conditions.

Laboratories may wish to retain instrument maintenance records for longer than the 2-year requirement (e.g. for the life of the instrument), to facilitate trouble-shooting.

Records of method performance specifications must be retained while the method is in use, and for at least two years afterwards. For requirements on retaining records of changes to software, the test library, and major functions of laboratory information systems, please refer to the Software section of the Laboratory Computer Services section of this checklist.

More stringent requirements for certain laboratory records (e.g. in anatomic pathology, cytopathology, transfusion medicine) may be found in the discipline-specific checklists.

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. 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.

In establishing retention requirements, care should be taken to comply with state and federal regulations.

Evidence of Compliance:
✓ Written policy for retention of records, specimens and slides

REFERENCES

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

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2005(Oct 1);1033 [42 CFR 493.1105(b)]
GEN.23584  Interim Self-Inspection  Phase II

The laboratory conducts an interim self-inspection and documents efforts to correct deficiencies identified during that process.

NOTE: The interim self-inspection is an important aspect of continuing education and laboratory improvement. The use of a variety of mechanisms for self-inspection (residents, technologists or other inspectors) is strongly endorsed. Documentation of performance of the interim self-inspection with correction of deficiencies is a requirement for maintaining accreditation. The laboratory must document that personnel responsible for each laboratory section have reviewed the findings of the interim self-inspection.

GEN.26791  Terms of Accreditation  Phase II

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

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

1. Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than 2 working days after the laboratory learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. CMS, State Department of Health, The Joint Commission, FDA, OSHA).

2. Change in laboratory test menu (notification must occur prior to starting new patient testing)

3. Change in location, ownership or directorship of the laboratory; notification must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than 2 working days afterwards

Evidence of Compliance:
✓ Records of notification, if applicable

GEN.30000  Monitoring Analytic Performance  Phase II

There is a written quality control program that clearly defines policies and procedures for monitoring analytic performance.

NOTE: The overall quality control program for the entire laboratory must be documented. It must include general policies and assignment of responsibilities. There must be clearly defined, written procedures for ongoing monitoring of analytic performance, including (1) number and frequency of controls; (2) establishment of tolerance limits for control testing; and (3) corrective actions based on quality control data. Quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director, supervisor or laboratory quality control coordinator).

GEN.30070  Verification of Accuracy  Phase II

If the laboratory performs test procedures for which neither calibration nor control materials are available, procedures are established to verify the reliability of patient test results.
NOTE: “Reliability” includes elements of accuracy, precision, and clinical discriminating power. This checklist requirement does not apply to waived tests.

SPECIMEN COLLECTION, DATA HANDLING, AND REPORTING

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

Inspector Instructions:

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

COLLECTION MANUAL AND OTHER DOCUMENTATION

Inspector Instructions:

- Sampling of specimen collection policies and procedures
- Reference laboratories policies and procedures
- Specimen collection manuals (available)

GEN.40000 Specimen Collection Manual

There is a procedure manual or other source for the complete collection and handling instructions of all laboratory specimens.

REFERENCES

GEN.40016 Collection Manual Biennial Review

There is documentation of at least biennial review of the specimen collection/handling procedure manual by the current laboratory director or designee.
**REVISED** 07/11/2011
GEN.40032 New Specimen Collection Procedure Review Phase II

The director reviews and approves all substantial changes to the specimen collection/handling procedure manual before implementation.

NOTE: Current practice must match policy and procedure documents.

GEN.40050 Distribution of Manuals Phase II

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.

**REVISED** 07/11/2011
GEN.40100 Specimen Collection Manual Elements Phase II

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

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

NOTE: Because of the importance of clinical information in the practice of surgical pathology and cytopathology, requisitions for such specimens should include pertinent clinical data, as well as pre-operative and/or post-operative diagnosis. Instructions should be documented for all applicable tissue and cytologic specimens, including biopsies, resections, PAP tests, sputum washings, brushings, body fluids, fine needle aspirations, etc. These instructions must be included in the procedure or user manuals at all sites where specimens are collected (e.g. nursing stations, clinics, physicians’ offices). 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, antibiotic therapy, etc.) or special instructions for collection, preservation, and storage (e.g. timed or 24-hour urine specimens).

REFERENCES
2) Burton JL, Stephenson TJ. Are clinicians failing to supply adequate information when requesting a histopathological investigation? J Clin Pathol. 2001;54:806-808
Referral Laboratory Specimen Handling

Phase II

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

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

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

REFERENCES

SPECIMEN COLLECTION

Accurate and precise laboratory data depends on properly performed phlebotomy to obtain a high quality specimen.

Inspector Instructions:

- Specimen collection (patient identification, specimen labeling, correction of labeling, and adverse event) policies and procedures
- Sampling of phlebotomy training records
- Paternity/forensic collection policies and procedures

- Sampling of phlebotomy supplies (expiration date, storage)
- Specimen collection at one or more sites within the institution.

- How is feedback related to specimen quality provided to the phlebotomist?

- If specimen collection errors are a recurring problem, further evaluate the laboratory’s investigation of how the errors occurred and the corrective actions that were implemented
**GEN.40460  Phlebotomy Supplies**

Phlebotomy supplies such as blood collection tubes are used within their expiration date and stored per manufacturer's instructions.

**GEN.40470  Specimen Collection Training**

There is documentation that all personnel performing patient blood collection have been trained in collection techniques and in the proper selection and use of equipment/supplies.

**NOTE:** This includes phlebotomists at remote sites that are owned and operated by the laboratory.

**REFERENCES**

1) Galena HJ. Complications occurring from diagnostic venipuncture. *J Fam Pract.* 1992;34:582-584

**GEN.40490  Patient Identification**

The individual collecting the specimen positively identifies the patient before collecting a specimen.

**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 identifying label must be attached to the specimen container(s) at the time of collection, and not deferred until a later time. The intent of this requirement is to ensure a documented, consistently followed system for correct patient sample identification at the point of collection.

*For example, verbal verification is not necessary if obtaining the services of a translator would delay specimen collection.
**Evidence of Compliance:**
✓ Written collection procedure defining criteria for patient identification

**REFERENCES**

**REVISED** 07/11/2011

**GEN.40491 Specimen Labeling**

**Primary specimen containers are labeled by at least 2 identifiers.**

**NOTE:** All primary specimen containers must be labeled with 2 identifiers at the time of collection. Submitted slides may be labeled with a single identifier, but two identifiers are preferred. 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.

The ‘primary’ specimen container is the innermost container received by the laboratory that actually holds the specimen.

In the outpatient setting, obtaining uniform compliance with this requirement may be difficult for the laboratory. In this setting, the laboratory should 1. Provide a list of acceptable identifiers to its clients; 2. Communicate with its clients regarding the importance of this requirement; and 3. Have a procedure for following up with clients when inadequately labeled specimens are received. Communication and follow-up may be through written memoranda, phone calls, visits by client service personnel, or other means of transport disclosure.

It is good laboratory practice to use two identifiers.

**Evidence of Compliance:**
✓ Written collection procedure defining criteria for labeling of primary specimen containers

**REFERENCES**

**GEN.40492 Specimen Label Correction**

**Phase I**

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

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

Evidence of Compliance:
✓ Records of corrections to specimen labels and corrective action

NOTE TO INSPECTOR: The following two requirements apply to laboratories that do not perform compatibility testing in-house, and for whom no Transfusion Medicine checklist is used.

GEN.40493 Compatibility Specimen Labeling

All blood samples used for compatibility testing are labeled at the time of specimen collection with the patient’s first and last name, unique identification number, and the date of collection.

NOTE: Before leaving the patient, blood specimens taken for compatibility testing must be positively and completely identified. Best practice is to use an electronic system to read the identifying information from the patient’s wristband and generate a label at the bedside.

Evidence of Compliance:
✓ Written procedure defining labeling requirements of specimens for compatibility testing

REFERENCES

GEN.40496 Phlebotomist Identification

If the specimen label does not have the initials or other identifier of the phlebotomist, there is another system to identify which person collected each blood sample for compatibility testing.

NOTE: There must be a system to identify the phlebotomist collecting blood samples for compatibility testing. The phlebotomist’s identification (initials or other unique identifier) may be indicated on the sample tube label or by some other acceptable method.

Evidence of Compliance:
✓ Written procedure defining system identifying the phlebotomist collecting compatibility testing specimens

GEN.40497 Paternity/Forensic Data

If the laboratory collects specimens for paternity/forensic identity testing, the following data are obtained:

1. Place and date of specimen collection
2. Identity of person collecting the specimen
3. Photograph, or photocopy of a picture identification card for each individual tested
4. Signed record of information (including name, race, relationship) for each individual tested
5. Date of birth of child
6. Synopsis of case history/investigation, sample source
7. Documentation of informed consent

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

REFERENCES
1) Standards for Parentage testing laboratories. American Association of Blood Banks. Standards for parentage testing laboratories. Bethesda, MD: 2003:5.2.4

GEN.40498 Specimen Labeling - Paternity/Forensic ID Phase II
For paternity/forensic identity testing, the information about each individual and the accuracy of the sample label is verified by that individual or the legal guardian.

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

GEN.40505 Phlebotomist Feedback Phase I
There is a mechanism to provide feedback to the collector of the specimen on issues relating to specimen quality.

NOTE: The accuracy of an analytic result depends upon the initial quality of the specimen. Proper phlebotomy technique are essential.

Evidence of Compliance:
✓ Written policy defining methods for providing feedback to phlebotomists AND
✓ Records of phlebotomy issues communication such as staff meeting minutes OR records of employee counseling

GEN.40508 Phlebotomy Adverse Reaction Phase I
The laboratory has procedures to care for patients who experience adverse reactions from phlebotomy.

NOTE: Adverse reactions include fainting, seizures and injuries. Immediate assistance should be available.

TRANSPORT SERVICES

This section addresses specimens received from remote locations outside of the facility in which the laboratory is located, as well as specimens referred by the laboratory to other locations. While transportation of clinical specimens may not be the responsibility of personnel under the control of the laboratory director, issues of tracking and specimen quality must be addressed to ensure quality laboratory results.

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

GEN.40511 Specimen Tracking/Labeling

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

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

REFERENCES
4) Tarapchak P. In 'shipping' shape. Advance/Lab. 2000;9(7):48-59

GEN.40512 Infectious Material Packing/Shipping

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

Evidence of Compliance:
✓ Records of review of applicable regulations

REFERENCES
4) Tarapchak P. In 'shipping' shape. Advance/Lab. 2000;9(7):48-59
5) Snyder JW. Packaging and Shipping of Infectious Substances. Clinical Microbiology Newsletter 24(12):89-93, June 2002

**REVISED** 07/11/2011

GEN.40515 Transport Personnel Training

Transport personnel are trained in appropriate safety and packaging procedures suitable to specimen type and distances transported, including certified 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 certified 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.
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).

For further information, please refer to:

http://hazmatonline.phmsa.dot.gov/services/publication_documents/ and

Evidence of Compliance:
✓ Records of training for all personnel involved in transport of specimens

REFERENCES
1) http://www.iata.org/dangerousgoods/index
2) http://www.phppo.cdc.gov/nltn/default.aspx
3) http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/06-4992.htm
4) http://hazmat.dot.gov/training/Transporting_Infectious_Substances_Safely.pdf

GEN.40530 Specimen Tracking

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

NOTE: Documentation 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 part of the laboratory organization, not to outside courier systems.

Evidence of Compliance:
✓ Specimen shipping/transport logs AND
✓ Records of follow up for specimens not received

GEN.40535 Specimen Transport QM

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

Evidence of Compliance:
✓ Records of corrective action OR communications with clients that frequently submit specimens incorrectly

REQUIREMENTS AND SPECIMEN RECEIPT/HANDLING/ASSESSMENT

Inspector Instructions:
**Laboratory General Checklist**

**07.11.2011**

- Sampling of specimen receipt and handling policies and procedures
- Sampling of specimen requisitions
- Sampling of temperature logs (refrigerator, freezer)

- How do you know what date/time a specimen is received in your laboratory? How are specimens accessioned once received by the laboratory?
- What is your course of action regarding verbal orders?
- How do you know your specimen containers do not contribute to analytic interference?

- If lost specimens are a recurring problem, further evaluate the laboratory's investigation of where/how in the process the specimen was lost and the corrective actions that were implemented

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**GEN.40700 Requisitions**

**Phase II**

All specimens are accompanied by an adequate requisition.

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

**REFERENCES**


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**GEN.40750 Requisition Elements**

**Phase II**

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

1. Adequate patient identification information (e.g., name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists)
2. Patient sex
3. Patient date of birth or age
4. Name and address (if different than the receiving laboratory) of physician or legally authorized person ordering the test
5. Tests requested
6. Last menstrual period (for gynecologic specimens)
7. Time and date of specimen collection when appropriate
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.

**REFERENCES**

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

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

REFERENCES

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

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

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

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

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

NOTE: The laboratory must retain the written authorization or documentation 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
Laboratory General Checklist

Evidence of Compliance:
✓ Records of follow-up to obtain written order

REFERENCES

GEN.40935 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.

GEN.40938 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 Specimen Container Analytic Interference

The laboratory evaluates its specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed.

NOTE: This may be done through some combination of direct testing by the laboratory, review of the clinical literature, and evaluation of information from manufacturers. It does not mandate exhaustive testing by each laboratory. "Inertness" of blood collection containers and specimen-contacting transfer devices and aliquot tubes cannot be assumed, as materials within these containers may lead to erroneous test results with medical consequences. Also, over- or underfilling vacuum tubes may lead to error.

Evidence of Compliance:
✓ Records of specimen container evaluation for analytic interference

REFERENCES

GEN.41017  Centrifuge Operating Speeds  Phase II

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

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

Evidence of Compliance:
✓ Records of verification of operating speeds documented at least annually

**REVISED**  07/11/2011  GEN.41042  Refrigerator/Freezer Temperatures  Phase II

Refrigerator/freezer temperatures are checked and recorded daily.

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 document appropriate corrective action, which may include evaluation of contents for adverse effects.

The two acceptable ways of recording temperatures are: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be documented (recording the initials of the individual is adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing that laboratory personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. The functionality of the system must be documented daily.

Patient samples may be stored in frost free freezers only if the temperature is monitored by a continuous monitoring system, or a maximum/minimum thermometer.

REPORTING OF RESULTS

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. Reference intervals (normal ranges) must be readily available to clinicians, preferably on the test report itself.

Inspector Instructions:
- Sampling of reporting policies and procedures
- Sampling of paper or electronic laboratory reports
- Sampling of referral laboratory’s patient reports
- HIPAA compliance policies and procedures
Laboratory General Checklist

07.11.2011

- How does the laboratory director ensure that the content of laboratory reports effectively communicates patient test results?
- How does the laboratory monitor compliance with HIPAA?
- What is your course of action if laboratory testing is delayed? How frequently does this occur?
- What is your process for selecting reference laboratories?
- How does your laboratory determine who is authorized to receive results?
- How does your laboratory archive test results for comparison with later results?

- If instances of delayed test reporting are frequent, further evaluate laboratory director leadership’s investigation, corrective actions, and resolution.
reporting system, one option is to include such results in a section of the electronic medical record other than the laboratory database.

**REVISED** 07/11/2011
GEN.41096 Report Elements Phase II

The paper or electronic report includes the following elements.

1. Name and address of testing laboratory (see note below)
2. Patient name and identification number, or unique patient identifier
3. Name of physician of record, or legally authorized person ordering test, as appropriate
4. Date and time of specimen collection, when appropriate
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 (see Note below)
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 reference laboratories where patient testing was performed. A “reference laboratory” includes outside reference 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 reference laboratories need not all be present on the same screen(s) as the results but must be available 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.

For urine testing for drugs of abuse, the cut-off value for positive results should be listed, either in the report or in a separate chart/memorandum that is available to clinicians.

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.

REFERENCES
3) Statland BE. Clinical decision levels for lab tests. Oradell, N.J: Medical Economics Books
GEN.41300  Report Retention and Retrieval  Phase II

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

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

GEN.41303  HIPAA  Phase II

**The laboratory complies with HIPAA.**

**NOTE:** The Health Information Portability and Accountability Act (HIPAA) is a federal law requiring protection of patients' health care information. The law requires maintenance of confidentiality when patient data is transmitted between two organizations. Also, organizations must establish appropriate relationships between sender and receiver of patient data to ensure that the information will be used as intended.

The laboratory should have policies and procedures delineating HIPAA compliance.

The laboratory must at least annually monitor compliance with HIPAA.

This checklist requirement applies only to laboratories subject to US regulations.

**Evidence of Compliance:**
✓  Written HIPAA compliance policy AND
✓  Records of HIPAA audit

**REFERENCES**

GEN.41304  Patient Data Accessibility  Phase II

There is a documented protocol in place to ensure that patient data are accessible only to those healthcare personnel who are authorized to review test results.

GEN.41306  Analyst Tracking ID  Phase II

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

**NOTE:** The system should also be capable of identifying those test results that have been autoverified.

**REFERENCES**

GEN.41307  Report Errors  Phase II

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

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

REFERENCES

**REVISED** 07/11/2011
GEN.41310 Revised Report Phase II

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

NOTE: 1. "Revised" means changes to patient results, accompanying reference intervals and interpretations, or patient identifiers, but not to minor typographical errors of no consequence. 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 revised information. The previous information and the revised information must be identified as such, and the original data must be present in the revised report (for paper reports), or linked electronically or logically to the revised 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. The format of corrected reports is at the discretion of the laboratory. For extensive interpretive or textual data (e.g. surgical pathology reports), replicating the entire original and corrected pathology reports may be cumbersome and render the revised report format difficult to interpret. In such cases, a comment in the corrected report summarizing the previous information and the reason for the correction may be provided.

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

GEN.41312 Multiple Revisions Phase I

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

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

GEN.41316 Infectious Disease Reporting Phase I

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

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 assure that its reporting system is effective.

**REVISED** 07/11/2011

**GEN.41345** Turnaround Time  Phase II

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

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

**Evidence of Compliance:**
✓ Written policy defining test reporting turnaround time and process for communication of delays in turnaround time

**REFERENCES**

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

The laboratory has a documented process for evaluating and selecting reference laboratories.

**NOTE:** The laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for selecting referral laboratories.

1. **Selection of reference laboratories must be based primarily upon the quality of performance of such laboratories**
2. "Referred Specimens" includes any for which intermediate processing is performed at another facility, such as histopathology/cytology preparation or nucleic acid sequencing
3. **For laboratories subject to US regulations:** for tests in disciplines covered by CLIA, specimens must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.* 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.
4. **For disciplines not covered by CLIA (e.g. histology), laboratories subject to US regulations must refer specimens to a laboratory accredited by CAP or a CAP-accepted organization.*
5. **For non-US laboratories, whenever possible, referral specimens should be sent 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.**
6. **It is the responsibility of the laboratory director or designee to monitor the quality of test results received from reference laboratories.**
The laboratory director should ensure that the reference laboratories provide turnaround times that meet clinical needs.

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

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

**Evidence of Compliance:**
- ✓ Records of the monitoring of reference laboratory services (e.g. problem log, review of reports)

**REFERENCES**
2. NCCLS. Selecting and evaluating a referral laboratory; approved guideline GP9-A. Wayne, PA: NCCLS, 1998

**GEN.41430 Reference Laboratory Report Retention**

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

**NOTE:** For results received directly from the testing laboratory’s computer, there may not be a paper copy, which is acceptable.

**Evidence of Compliance:**
- ✓ Retained original reference laboratory reports OR direct access to reference laboratory reports via electronic transmission from the reference laboratory

**REFERENCES**

**GEN.41440 Reference Laboratory Results Reporting**

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

**NOTE:** This does not mandate that the referring laboratory report every word nor retain the exact format of the reference laboratory report. Beyond faithful transcription of any direct testing data, the referring laboratory director may elect to edit interpretive remarks provided by the reference laboratory, in the context of patients’ clinical status and the local medical environment. There is no requirement to fully replicate the complete content of the reference laboratory report.

**Evidence of Compliance:**
- ✓ Patient results from the reference laboratory consistent with laboratory-issued patient reports

**REFERENCES**
DIRECT-TO-CONSUMER TESTING

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

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

GEN.41460 DTC Jurisdiction Phase II
The laboratory performs DTC testing and reports results of DTC tests only in jurisdictions where such testing is lawful.

NOTE: No less than every 2 years, the laboratory must verify which jurisdictions permit DTC testing.

Evidence of Compliance:
✓ Documentation that the laboratory has reviewed applicable laws/regulations

GEN.41475 DTC Report Phase II
The test report includes test results, reference range, interpretation as applicable, and limitations of the test, as applicable, in language readily understandable by a lay person.

**REVISED** 07/11/2011
GEN.41485 DTC Report Phase II
The test report includes information that enables the consumer to contact a licensed health care professional about the clinical significance of the test result.

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

The practitioner or designee should be reasonably available during normal business hours.

GEN.41497 DTC Result Retention Phase II
The laboratory retains the results of DTC tests and reference ranges for at least 10 years after testing.

NOTE: This requirement applies only to DTC tests performed after June 15, 2009.
QUALITY OF WATER AND GLASSWARE WASHING

Inspector Instructions:

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

**REVISED** 07/11/2011
GEN.41500 Defined Water Types Phase II

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

**NOTE:** The laboratory should define the type of water necessary for each of its procedures, and should have an adequate supply of same. The current edition of CLSI Guideline C3-A4 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 similar to the Type I reagent water defined in earlier editions of this guideline.

CLRW is not required if the laboratory is able to document 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 documented 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 documented if water does not meet acceptability criteria.

For CLRW, minimum monitoring includes resistivity and microbiology cultures. Other criteria, such as pH, endotoxin/pyrogens, silicates and organic contaminants are at the discretion of the laboratory, testing for these substances must be documented 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.

<table>
<thead>
<tr>
<th></th>
<th>CLRW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum microbial content (CFU/mL)</td>
<td>10</td>
</tr>
<tr>
<td>Minimum resistivity (megohm-cm)</td>
<td>10 (in-line)</td>
</tr>
<tr>
<td>Particulate matter</td>
<td>0.22 um filter</td>
</tr>
</tbody>
</table>

**Evidence of Compliance:**
✓ Documentation of corrective action when water quality does not meet specifications

**REFERENCES**
8) Stewart BM. The production of high-purity water in the clinical laboratory. Lab Med. 2000;31:605-611

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

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

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

**Evidence of Compliance:**
✓ Records of detergent residue testing

**REFERENCES**
Multiple solutions for laboratory information systems (LIS) exist. Traditional systems have a local “host” database (i.e. the computer hardware and software) serving the information needs of the laboratory; the laboratory is the only “user.” In the current environment, the host is often physically remote from the laboratory and in fact the host may have multiple user laboratories. Many of the Computer Services requirements may apply to host, user, or both, depending on how information services are organized in the laboratory. For laboratories which do not have host functions on site, the inspector should mark nonapplicable requirements N/A. However, the laboratory is responsible for ensuring that the provider of host functions meets CAP requirements (see GEN.42195, below).

The requirements in this section do NOT apply to the following:

1. Desktop calculators
2. Small programmable technical computers
3. Purchased services such as the Quality Assurance Service or Laboratory Management Index Service of the College of American Pathologists
4. Micro computers used solely for word processing, spreadsheets, or similar single user functions
5. Dedicated microprocessors or workstations that are an integral part of an analytic instrument

Inspector Instructions:

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

GEN.42195 Remote LIS Phase II

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

NOTE: This requirement does not apply if all components of the LIS are under the laboratory’s CAP/CLIA 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 items, with documentation provided to the laboratory director and the CAP inspector.

COMPUTER FACILITY

This section applies to laboratories where the computer facilities are housed. If the computer facilities are located at another site, go to the LIS/Computer Procedure Manual section.

Inspector Instructions:

- Computer facility equipment and location (clean, ventilated, protected against power surges)
- Fire extinguishers/equipment
GEN.42750 Computer Facility Maintenance Phase I

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

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

GEN.42800 LIS Fire Equipment Phase II

Fire-fighting equipment (extinguishers) is appropriate for electrical components available.

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

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

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

REFERENCES

GEN.42900 LIS Power Phase II

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

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

LIS/COMPUTER PROCEDURE MANUAL

Inspector Instructions:

- Sampling of LIS/computer policies and procedures
GEN.42950  LIS Procedures  Phase II

LIS/computer procedures are clearly documented, complete and readily available to all authorized users.

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. It is not required for all procedures to be kept in a single manual, as long as the users have access to the procedures they need to perform their job duties. Current practice must match policy and procedure documents.

GEN.43000  LIS Procedure Biennial Review  Phase II

There is documentation that laboratory computer procedures are reviewed at least biennially by the laboratory director or designee.

NOTE: A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

HARDWARE AND SOFTWARE

Inspector Instructions:

- Sampling of hardware and software policies and procedures
- Sampling of computer training records

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

GEN.43022  LIS Testing  Phase II

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

NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications. Any changes or modifications to the system must be documented, 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. Documentation must be retained for at least two years beyond the service life of the system.

GEN.43033  Custom LIS  Phase II

Customized programs are appropriately documented.

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

**GEN.43044** Software Modification Tracking  Phase II

There is an adequate tracking system to identify all persons who have added or modified software.

Evidence of Compliance:
✓ Records of individuals adding or modifying software

**GEN.43055** LIS Training  Phase II

There is documentation that all users of the computer system receive adequate training initially, after system modification and after installation of a new system.

**REVISED**  07/11/2011

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

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

Evidence of Compliance:
✓ Written LIS policy with instructions for contacting a responsible person in case of system malfunction

**GEN.43088** LIS Integrity  Phase II

There is a documented process to verify the integrity of the system (operating system, applications and database) after restoration of data files.

NOTE: The computer system must be checked after restoration of data files to ensure that no inadvertent alterations have occurred that might affect clinical result reporting. The integrity of the system may be verified, for example, by review of a representative number of computer-generated patient reports, or by generating test (“dummy”) patient reports for review. The laboratory director is responsible for determining verification procedure(s) appropriate to the laboratory. Whether or not the data center is located on site, all facilities served by the data center must participate in the verification of the system(s) integrity following a hardware or software failure.

Evidence of Compliance:
✓ Records of verification after a hardware or software failure

**SYSTEM MAINTENANCE**

**Inspector Instructions:**
- Sampling of LIS maintenance, service and repair records
Laboratory General Checklist

**NEW**       07/11/2011

GEN.43090  Data/Services Protection  Phase II

Data and services are protected from loss.

NOTE: Policies and procedures must 1. Be adequate to address scheduled and unscheduled interruptions of power or function; 2. Be tested periodically for effectiveness; 3. Include systems to backup programs and data; and 4. Include a written plan.

SYSTEM SECURITY

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

Inspector Instructions:

- Sampling of computer security policies and procedures

GEN.43150  Access Patient Data  Phase II

There are explicit documented policies that specify who may use the computer system to enter or access patient data, change results, change billing or alter programs.

NOTE: Policies must define those who may only access patient data and users who are authorized to enter patient results, change results, change billing, or alter computer tables or programs.

GEN.43200  Computer Access Codes  Phase I

Computer access codes (security codes, user codes) are in place to limit individuals’ access to those functions they are authorized to use, and the security of access codes is maintained (e.g. inactivated when employees leave, not posted on terminals).

NOTE: The laboratory should establish security (user) codes to permit only specifically authorized individuals to access patient data or alter programs. A system that allows different levels of user access to the system based on the user’s authorization is desirable and usually provides effective security. Examples of best practices include these requirements: 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.

GEN.43262  Unauthorized Software Installation  Phase I

Policies and procedures are in place 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.

Gen.43325 Public Network Security Phase II

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

NOTE: Information sent over a public domain such as the Internet is considered in the public domain. Thus it is potentially accessible to all parties on that network. Systems must be in place to protect network traffic, such as "fire walls" and data encryption schemes.

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

PATIENT DATA

Inspector Instructions:
- Documentation of the review of patient results containing calculated data
- How are absurd values detected?
- How does the technologist electronically enter comments regarding specimen quality?
- How does your laboratory verify manual and automated result entry?

**REVISED** 07/11/2011
Gen.43450 Calculated Patient Data Verification Phase II

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

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

Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked and documented to ensure accuracy. 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 (for example, 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 a copy of the review documentation. However, any calculations specific to an individual laboratory's methodology must be reviewed by that laboratory and the documentation of that review must be available.

Evidence of Compliance:
✓ Records of validation of calculated test results
GEN.43750  Specimen Quality Comment  Phase II

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

Evidence of Compliance:
✓  Patient reports

GEN.43800  Data Input ID  Phase II

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

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

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

REFERENCES
1)  Jones JB. The importance of integrating POCT data into an organized database. Advance/Laboratory. 1999;8(9):8-10

GEN.43812  Test Result Routing  Phase I

The laboratory has a process to ensure appropriate routing of patient test results to physicians.

NOTE: During the course of their medical care in a health care system, the location of a patient may change multiple times; i.e. from various inpatient locations, to outpatient, to physician office patient. The intent of the requirement is to ensure that patient test results are routed to the responsible physician(s) regardless of patient location. For example, after a patient is discharged from the hospital test reports should be routed to the physician as well as the hospital medical record.

Evidence of Compliance:
✓  Written policy defining process for routing of patient results

GEN.43825  Result Verification  Phase II

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

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

GEN.43837 Downtime Result Reporting

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

REFERENCES

AUTOVERIFICATION

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

Inspector Instructions:
- Autoverification policies and procedures
- Autoverification validation

GEN.43850 Autoverification Approval

There is a policy signed by the laboratory director approving the use of autoverification procedures.

REFERENCES
1) Davis GM. Autoverification of the peripheral blood count. Lab Med. 1994;25:528-531
2) Davis GM. Autoverification of macroscopic urinalysis. Lab Med. 1999;30:56-60
5) Duco DJ. Autoverification in a laboratory information system. Lab Med. 2002;33:21-25

GEN.43875 Autoverification Validation

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

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

GEN.43878 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.

GEN.43881 Autoverification Result Comparability

Results are compared with an appropriate range of acceptable values 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.)

Evidence of Compliance:
✓ Records of system rules including comparison of patient results against absurd and critical values

GEN.43884 Result Flags

Results are checked for flags or warnings prior to autoverification.

NOTE: 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.

GEN.43887 Autoverification Audit Trail

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

GEN.43890 Autoverification Delta Checks

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

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

Evidence of Compliance:
✓ Records of system rules including the use of delta checks when appropriate

GEN.43893 Autoverification Suspension

The laboratory has a procedure for rapid suspension of autoverification.

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

Inspector Instructions:

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

GEN.43900 Archived Test Result

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

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

GEN.43920 Multiple Analyzer ID

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

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

GEN.43946 Data Preservation/Destructive Event

There are documented procedures for the preservation of data and equipment in case of an unexpected destructive event (e.g. fire, flood), software failure and/or hardware failure, and these procedures allow for the timely restoration of service.

NOTE: These procedures can include (but are not limited to) steps to limit the extent of the destructive event, protocols for periodic backing up and storing of information, procedures for off-site storage of backup data, and protocols/procedures for restoring information from backed up media. The procedures should specifically address the recoverability of patient information. Changes to hardware and software commonly require review and reevaluation of these documented procedures. These procedures must specifically address the physical environment and equipment. This checklist requirement is often addressed by the organization’s disaster plan.

REFERENCES

INTERFACES
**Inspector Instructions:**

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

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

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

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

**GEN.47000**  Interface Security  Phase II

If data in other computer systems can be accessed through the LIS (e.g. pharmacy or medical records), there are documented policies to prevent unauthorized access to that data through the LIS.

**REVISED** 07/11/2011

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

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

*NOTE:* Verification must be performed prior to implementation of an interface (i.e. pre go-live), and every 2 years thereafter. This includes evaluation of data transmitted from the LIS to other computer systems and their output devices. Reference ranges and comments, as well as actual patient results and report formats, must be evaluated.

Verification of accurate data transmission from the LIS to other systems must be performed by reviewing data in the first downstream (or interfaced) system in which the ordering clinician/client (e.g. referring laboratory) may be expected to routinely access patient data. This requirement can be met by printing screen shots or by other methods that document that a verification procedure has been performed. 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.

At implementation of a new interface, or change to an existing interface, validation of at least 2 examples of reports from each of the following disciplines, where applicable, satisfies the intent of this checklist requirement. Subsequently, at least 2 examples of reports from at least 4 of
these disciplines should be validated every 2 years. Not all of these report types will be applicable to every laboratory:

1. Surgical pathology reports
2. Cytopathology reports (preferably gynecologic and non-gynecologic)
3. Clinical laboratory textual reports (e.g. molecular, protein electrophoresis, coagulation panel interpretation)
4. Quantitative results (e.g. chemistry, hematology, or coagulation)
5. Qualitative or categorical results (e.g. serology)
6. Microbiology reports (e.g. culture and antimicrobial sensitivity)
7. Blood bank reports (e.g. type and screen)

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

Evidence of Compliance:
✓ Records of verification

REFERENCES

GEN.48750 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.

REFERENCES

TELEPATHOLOGY

This section applies to telepathology. Telepathology is the practice of pathology, in which the pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record.

Telepathology modes include:
- Static telepathology – interpretation based on pre-selected still image(s)
- Dynamic telepathology - viewing real-time images
- 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

This checklist section is NOT applicable to:
- Informal reviews without formal reporting
- Image analysis, in which the image is not interpreted by a pathologist, such as urine analysis
- Educational or research use of these systems

**Inspector Instructions:**

- Sampling of telepathology policies and procedures

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**GEN.50057 Slide/Image ID**

**Phase II**

There is a method for the telepathologist to ensure that correct patient identification and slides/images are submitted for review.

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

**Evidence of Compliance:**

✓ Written procedure defining mechanism to positively identify slides/images

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**GEN.50614 Clinical Information Access**

**Phase I**

The telepathologist has access to pertinent clinical information at the time of slide/image(s) review.

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

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**GEN.51171 Telepathology Appropriate Use**

**Phase I**

The methods and systems in place ensure that the system used for telepathology is appropriate for its intended clinical use.

*NOTE:* There should be a policy statement in the procedure manual that identifies appropriate and inappropriate use cases. For example, if a dynamic telemicroscopy system is installed on a microscope in the frozen section suite, the manual might state that this system is intended for use in intra-operative consultation and is not intended for second opinion consultation from pathologists at outside institutions.

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**GEN.51728 Telepathology Training**

**Phase I**

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

**Evidence of Compliance:**

✓ Records for telepathology training in personnel files

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**GEN.52842 Telepathology and HIPAA**

**Phase II**

There are procedures in place to ensure that sites engaging in telepathology provide reasonable confidentiality, security and conformance to HIPAA requirements.
NOTE: Procedures might include message security, system and user authentication, activity logs, encryption, and access restrictions.

PERSONNEL

The laboratory should have an organizational chart, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files should contain qualifications, references, performance evaluations, health records and continuing education records for each employee. Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (i.e., they are easily available to the inspector).

Inspector Instructions:

- Sampling of personnel policies and procedures
- Organizational chart or narrative description
- Technical supervisors’ qualifications
- Sampling of competency assessments
- Sampling of technical personnel files using the table below:

<table>
<thead>
<tr>
<th>Total Number of Technical FTE's in Laboratory</th>
<th>Number of Personnel Records to Randomly Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 10</td>
<td>Review all personnel</td>
</tr>
<tr>
<td>11 - 100</td>
<td>8 - 10</td>
</tr>
<tr>
<td>101 - 250</td>
<td>10 - 12</td>
</tr>
<tr>
<td>251 - 400</td>
<td>13 - 15</td>
</tr>
<tr>
<td>401 - 500</td>
<td>16 - 18</td>
</tr>
<tr>
<td>More than 500</td>
<td>18 - 20</td>
</tr>
</tbody>
</table>

- Do you have a specific example of an employee who demonstrated unacceptable competency assessments? What were the corrective actions?
- What continuing education classes are available to employees?

TECHNICAL SUPERVISORS

This is a position title defined under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) for laboratories performing high complexity tests. The technical supervisors, as designated by the laboratory director, are responsible for the technical and scientific oversight of the laboratory. Within the laboratory’s organizational structure, the actual position title may be different. A qualified laboratory director may serve as the technical supervisor, and may set position requirements more stringent than CLIA. If the laboratory performs only waived and/or moderate complexity tests, or is not subject to US regulations, this subsection is not applicable.

**REVISED** 07/11/2011
GEN.53400 Technical Supervisor Qualifications/Requirements Phase II

Technical supervisors meet the qualifications and fulfill the responsibilities defined by
CLIA.

NOTE: The technical supervisor in each high complexity laboratory section can be a licensed MD or DO with certification in anatomic and/or clinical pathology, or qualifications equivalent to those required for board certification. The technical supervisor responsible for anatomic pathology must be an MD or DO certified in anatomic pathology or possess qualifications equivalent to those required for certification. The technical supervisor responsible for clinical pathology must be an MD or DO certified in clinical pathology or possess qualifications equivalent to those required for certification; or may be an individual who meets the alternate qualifications in the CLIA regulations (42CFR493.1449) for the specialties supervised. If the technical supervisor is responsible for both anatomic and clinical pathology, then he/she must be certified in both anatomic and clinical pathology or possess qualifications equivalent to those required for certification.

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, diagnostic immunology, chemistry, hematology, cytology, ophthalmic pathology, dermatopathology, oral pathology, radiobiology, immunohematology.

CLIA imposes additional requirements for the technical supervisors of the histocompatibility and clinical cytogenetics services. These are found in the Histocompatibility and Cytogenetics Checklists, respectively.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

REFERENCES

GENERAL SUPERVISORS

This is a position title defined under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) for laboratories performing high complexity tests. The general supervisor of high-complexity testing, as designated by the laboratory director, is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Within the laboratory’s organizational structure, the actual position title may be different. A qualified laboratory director may also serve as the general supervisor, and may set position requirements more stringent than CLIA. If the laboratory performs only waived and/or moderate complexity tests, or is not subject to US regulations, this section is not applicable.

**REVISED**
07/11/2011
GEN.53600

General Supervisor Qualifications/Requirements

General supervisors meet the qualifications and fulfill the responsibilities defined by CLIA.

NOTE: The qualifications for general supervisor can be the same as that of laboratory director or technical supervisor. Less stringent educational backgrounds are federally recognized, including:

1. Bachelor’s degree in a chemical, physical, biological or clinical laboratory/medical technology science with at least one year experience with high complexity testing, or
2. Associate degree in a laboratory science or medical technology program with at least two years experience with high complexity testing, or
3. Previously qualified or could have qualified as a general supervisor prior to 2/28/92 under 42CFR493.1427 (3/14/90)
CLIA requirements for the general supervisors of cytopathology and blood gas analysis are found in the Cytopathology checklist and Chemistry and Toxicology checklist.

**Evidence of Compliance:**
- ✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

**REFERENCES**

### ALL PERSONNEL

**GEN.54000** Organizational Chart

**Phase II**

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

**GEN.54100** Personnel Policies

**Phase II**

There are documented personnel policies.

**GEN.54200** Continuing Education

**Phase I**

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

**Evidence of Compliance:**
- ✓ Written policy for continuing laboratory education

**REFERENCES**
4) Yapit MK. Resources and strategies for a successful CE program. Med Lab Observ. 1989(Apr):47-566

**REVISED** 07/11/2011

**GEN.54400** Personnel Records

**Phase II**

Personnel files are maintained on all current technical personnel and personnel records include all of the following items.

1. Summary of training and experience
2. Copy of academic degree or transcript
3. License, if required by state
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 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

REFERENCES

GEN.54750 Testing Personnel Qualifications
Phase II
For laboratories subject to US federal regulations, all testing personnel meet CLIA requirements.

NOTE: High complexity testing personnel must have an earned associate degree in a laboratory science or medical laboratory technology from an accredited institution, or equivalent laboratory training as delineated in 493.1489 or 493.1491. Moderate complexity testing personnel must have an earned high school diploma or equivalent, and documented training as delineated in 493.1423. For further details please refer to http://www.cms.hhs.gov/clia.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

REFERENCES

GEN.55400 Visual Color Discrimination
Phase I
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.

Evidence of Compliance:
✓ Record of color discrimination testing OR functional assessment, if indicated

**NEW**

06/17/2010

GEN.55450 Initial Training
Phase I
There is documentation that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

NOTE: The records must show that training specifically applies to the testing performed by each individual.

Retraining must occur when problems are identified with employee performance.
The competency of each person to perform his/her assigned duties is assessed.

NOTE: The competency of each person to perform the duties assigned must be assessed following training before the person performs patient testing. Thereafter, 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 annually. Retraining and reassessment of employee competency must occur when problems are identified with employee performance. Elements of competency assessment include but are not limited to:

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

Other elements of competency may be assessed, as applicable. A laboratory must evaluate and document the competency of all testing personnel for each test system. 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.

The laboratory must identify the test systems that an employee uses to generate patient test results. Many of the elements of competency assessment are performed during routine supervisory review of an employee. Documentation of these elements, including 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 by 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 documented by a checklist. For nonwaived test systems, all the above six elements must be assessed annually (unless any are not applicable to the test system). For waived test systems, the laboratory may select which elements to assess.

Evidence of Compliance:
✓ Records of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation

REFERENCES

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

If an employee fails to demonstrate satisfactory performance on the competency assessment, the laboratory has a plan of corrective action to retrain and reassess the employee's competency.

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

**Evidence of Compliance:**
✓ Records of corrective action to include evidence of retraining and reassessment of competency

**PHYSICAL FACILITIES**

**Inspector Instructions:**

- Physical facility (adequate space, acceptable temperature/humidity, areas clean, adequate storage areas, adequate emergency power)
- Is the work area sufficient for you to perform your duties safely and accurately?

**SPACE**

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

**GEN.60000 Adequate Space Phase II**

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

**REFERENCES**
1) Koenig AS. Medical laboratory planning and design. Northfield, IL: College of American Pathologists, 1992
GEN.60100 Adequate Space Phase I

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

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

ENVIRONMENT

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

GEN.61300 Climate Control Phase I

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

Evidence of Compliance:
✓ Temperature and humidity records, if specific ranges are required for instrument and/or reagent use

GEN.61400 Hallway Obstructions Phase I

Passageways are unobstructed.

GEN.61500 Environment Maintenance Phase I

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

GEN.61600 Environment Maintenance Phase I

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

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

GEN.61750 Hand-Off Communication

The laboratory implements a procedure for effective “hand-off” communication.

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

Evidence of Compliance:
✓ Logs or message boards showing communication between shifts

GEN.61800 Telephone/Computer Locations

Telephones and computer terminals are conveniently located.

INVENTORY AND STORAGE OF SUPPLIES

GEN.61900 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.

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

GEN.62000 Intralaboratory Storage

The intralaboratory storage area is sufficient and free of clutter.

POWER

GEN.66100 Emergency Power

Emergency power is adequate for the functioning of the laboratory.

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

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

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

SAFETY POLICIES AND RECORDS

Inspector Instructions:

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

GEN.73200 Safety Policy Approval

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

GEN.73300 Safety Policy Availability

Safety policies and procedures are posted or readily available to all personnel.

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

REFERENCES

**REVISED** 07/11/2011
GEN.73400 Safe Work Practices Review Phase II
There is documented periodic review (at least annually) of safe work practices to reduce hazards.
NOTE: Review must include bloodborne hazard control and chemical hygiene.
Evidence of Compliance:
✓ Safety committee minutes OR records of regular safety inspections OR incident reports and statistics OR another method defined by the laboratory director

REFERENCES

GEN.73500 Safety Policy Lab Accidents Phase II
Policies and procedures are developed regarding the documentation of all laboratory accidents resulting in property damage or involving spillage of hazardous substances.

GEN.73600 Occupational Injuries Phase II
Policies and procedures are developed regarding the reporting of all occupational injuries or illnesses that require medical treatment (except first aid).
NOTE: For US laboratories, all serious accidents resulting in fatalities or in the hospitalization of 3 or more employees must be reported to the Occupational Safety and Health Administration (OSHA) within 8 hours.

REFERENCES

**REVISED** 07/11/2011
GEN.73700 Occupational Injury Evaluation Phase II
An evaluation of these reports of laboratory accidents and occupational injury/illnesses is incorporated into the laboratory’s quality management program to avoid recurrence.
Evidence of Compliance:
✓ Records of report evaluation OR committee minutes with records of discussion

GEN.73800 Disaster Preparedness Phase II
Policies and procedures are documented and adequate for internal and external disaster preparedness.
There is a comprehensive, documented and workable evacuation plan for the laboratory, including specific plans for any persons with disabilities.

NOTE: 1. This plan must cover all employees, patients and visitors, and should address the special needs of persons with disabilities. Evacuation routes must be clearly marked (Posting evacuation routes is optional). 2. Emergency lighting is adequate for safe evacuation of the laboratory.

REFERENCES
1) Occupational Safety and Health Administration. Exit routes, emergency action plans, and fire prevention plans: standard, 2002 [29CFR1910.38]

BLOODBORNE PATHOGENS

Inspector Instructions:

- Sampling of safety policies and procedures
- Sampling of records of hepatitis B vaccination or records declining the vaccination
- Sampling of personnel safety education records
- PPE usage
- What has your laboratory done to reduce or eliminate exposure to bloodborne pathogens during phlebotomy and laboratory testing?
Evidence of Compliance:
✓ Safety policy manual AND
✓ Records of universal precaution training for all personnel expected to have contact with body fluids

REFERENCES

GEN.74100 PPE Provision and Usage
Phase II

Appropriate personal protective equipment (gloves, gowns, masks and eye protectors, etc.) is provided and maintained in a sanitary and reliable condition in all technical work areas in which blood and body substances are handled and in circumstances during which exposure is likely to occur.

NOTE: 1. Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious materials to pass through or reach the employee’s work clothes, skin, etc. In addition to fluid-resistant gowns, aprons may be required if exposure to large volumes of body fluids is anticipated. 2. OSHA requires gloves to be worn with each patient contact and changed after contact when performing vascular access procedures, except when drawing voluntary blood donors.

REFERENCES

GEN.74200 PPE Instruction
Phase II

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

NOTE: 1. Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious material to pass through to the skin. Footwear must provide adequate protection. 2. 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.

Evidence of Compliance:
✓ Written procedure for the use of PPE for specific tasks AND
✓ Records of personnel training for PPE

REFERENCES
Manual Manipulation of Needles


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

**REFERENCES**

Eating/Mouth Pipetting


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

**REFERENCES**

Specimen Transport Procedures


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

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

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

Evidence of Compliance:
✓ Written policy offering the hepatitis B vaccination to employees AND
✓ Records of vaccination OR records signed by employees declining the vaccine

REFERENCES

GEN.74800  Viral Exposure  Phase II

There is a program for follow-up procedures 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 the healthcare worker
3. Follow-up procedures including consideration of appropriate prophylaxis for personnel acutely exposed to HIV, HBV or HCV, based upon medical indications, the serologic status and the informed consent of the health-care worker
4. Reporting of the exposure as required by law

Evidence of Compliance:
✓ Records of exposure follow-up consistent with policy

REFERENCES

OTHER INFECTIOUS HAZARDS

Inspector Instructions:
- Sampling of safety policies and procedures
- Sampling of sterilizing device monitoring records

GEN.74900  TB Exposure Plan  Phase II

The laboratory has a documented tuberculosis exposure control plan.

NOTE: This plan must include an exposure determination at defined intervals for all employees
who may have occupational exposure to tuberculosis. Additional elements of the plan include engineering and work practice controls for hazardous procedures that potentially may aerosolize Mycobacterium tuberculosis. Such procedures include the handling of unfixed tissues in surgical pathology or autopsies, and processing of specimens in the microbiology section from patients with suspected or confirmed tuberculosis.

If respiratory protection is needed because of potential exposure to an infectious agent by aerosol or droplet, personnel should use either a properly fit-tested NIOSH-approved filter respirator (N-95 or higher) or a powered air-purifying respirator (PAPRS) equipped with high efficiency particulate air (HEPA) filters. Accurate fit testing is a key component of effective respirator use.

REFERENCES

GEN.75000 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.

Evidence of Compliance:
✓ Written procedure defining monitoring process for sterilizing devices AND
✓ Records of monitoring documented at defined frequency

FIRE PREVENTION AND PROTECTION

Inspector Instructions:

READ
• Sampling of safety policies and procedures
• Sampling of employee fire exit drill attendance records
• Sampling of employee fire extinguisher training records

OBSERVE
• Automatic fire extinguisher systems, if required
• Two exit access doors, if required
• Audible automatic fire detection and alarm system
• Fire alarm station
• Portable fire extinguishers, where appropriate

GEN.75100 Fire Prevention Policies

Policies and procedures are documented and adequate for fire prevention and control.

REFERENCES
GEN.75200

Fire Separation

Phase II

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

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

For those facilities with inpatients, where the laboratory is separated by 2-hour construction (rated at 1.5 hours) and Class B self-closing doors (SCD), no AFE system is required. Unless there are unattended laboratory operations employing flammable or combustible reagent, an AFE system is required. An AFE system is required for those laboratories separated from inpatient areas by 1-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 2 gallons of Class I, II, and IIIA liquids in safety cabinets and safety cans per 100 ft², or half that amount if not in safety containers. The following are the definitions of these Classes:

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

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

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

REFERENCES


GEN.75300

Fire Exit

Phase II

Each room larger than 1000 ft², or in which major fire hazards exist, has at least 2 exit access doors remote from each other, one of which opens directly into an exit route.

REFERENCES


GEN.75400

Annual Fire Drill

Phase II

Fire drills are conducted at least annually.

NOTE: Fire exit drills must prepare employees to respond safely in the event of fire. Announced or unannounced drills must be held in the laboratory. The purpose of a fire exit drill is to educate the occupants in the facility’s fire safety features and exits, and to test the ability of institutional personnel to implement the facility’s fire emergency plan. It also is an evaluation of the escape routes, especially in larger buildings. The fire exit drill will 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). For these reasons personnel must actually exit the area. Paper or computerized testing of an individual’s fire safety knowledge is not sufficient. All personnel must participate at least once a year, but a single drill may involve only a subset of the personnel in attendance. Interruption in essential laboratory services is not required.
Evidence of Compliance:
✓ Records of participation for all employees in fire drills involving laboratory evacuation at least annually (e.g. employee roster with dates of participation)

REFERENCES

GEN.75500 Fire Detection/Alarm Phase II

There is an automatic fire detection and alarm system.

NOTE: 1. The system must connect to the facility’s overall system, where such a system exists. It should sound an immediate alarm in the event of smoke or fire. 2. The fire alarm is audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms. 3. Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.

REFERENCES

GEN.75600 Fire Alarm Station Phase II

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

NOTE: OSHA and National Fire Protection Association (NFPA) Standards require fire alarm facilities in every building where a fire may not itself provide adequate warning. Fire alarm systems should be reliable and meet NFPA Standards. A telephone network is inadequate in most situations.

REFERENCES

GEN.75700 Fire Extinguishers Phase II

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

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

REFERENCES

GEN.75800 Fire Extinguishers Phase II

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

Evidence of Compliance:
✓ Records for fire extinguisher training for all personnel

REFERENCES

ELECTRICAL SAFETY

Inspector Instructions:
- Sampling of electrical grounding records, if applicable

GEN.75900 Electrical Grounding

There is documentation that both the laboratory director and the institutional safety committee have approved a program to ensure 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. Equipment operating at 240 v must be checked for ground integrity only

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

REFERENCES

CHEMICAL SAFETY

Inspector Instructions:
- Sampling of chemical safety policies and procedures
- Sampling of MSDS sheets
The laboratory has a Chemical Hygiene Plan (CHP) that defines the safety procedures for all chemicals used in the laboratory.

**NOTE 1:** The laboratory director or designee must ensure that the laboratory has a documented chemical hygiene plan (CHP) that defines the safety procedures 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 employees. 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, material safety data sheets and employee training. An acceptable CHP contains the following elements:

1. Responsibilities of the laboratory director and supervisors
2. Designation of a chemical hygiene officer
3. Policies for all operations that involve chemicals
4. Criteria for the use of personal protective equipment and control devices
5. Criteria for exposure monitoring when permissible levels are exceeded
6. Provisions for medical consultations and examinations
7. Provision for training employees in 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
10. Specific handling requirements for all hazardous chemicals used in the laboratory

**NOTE 2:** Chemicals that must be handled as potential carcinogens include those defined by OSHA as "select carcinogens." OSHA defines select carcinogens as any substance that is:

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

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

Authoritative sources include (but are not limited to) OSHA (Code of Federal Regulations, Title 29, Part 1910.10011047, 1450); NIOSH (Registry of Toxic Effects of Chemical Substances); the National Toxicology Program; the International Agency for Research on Cancer, and Material Safety Data Sheets.

**Evidence of Compliance:**
✓ Written evaluation of chemicals used in the laboratory for carcinogenic potential, reproductive
toxicity and acute toxicity *AND*

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

REFERENCES

GEN.76100 MSDS

Phase II

For US laboratories, employees have access to all of the following documents.

1. Current Material Safety Data Sheets and other references that list the details of hazards and the precautions for safe handling and storage
2. Chemical Hygiene Plan of the laboratory

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

GEN.76200 Chemical Precautionary Labels

Phase II

Precautionary labels are present on the containers of all hazardous chemicals (flammable liquids Classes I, II and IIIA; corrosives; irritants; asphyxiants; potential carcinogens; etc.), 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 employees 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 employee who performs the transfer. Existing labels on incoming containers of hazardous chemicals shall not be removed or defaced, unless the container is immediately marked with the required information.

REFERENCES

GEN.76300 PPE And Hazardous Materials

Phase II

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

NOTE: Such devices may include gloves of appropriate composition, aprons, and eye protection. Open-toe footwear does not provide adequate protection and should not be worn in the laboratory.

REFERENCES
GEN.76400  Hazardous Material Emergency Treatment  Phase II

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

NOTE: Spill kits must be handled in accordance with manufacturer instructions. If no expiration date is assigned, the spill kit must indicate the date it was put into service and the director must periodically assess its usability.

REFERENCES

GEN.76500  Flammable Storage  Phase II

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

NOTE: 1. In each laboratory area, up to 1 gallon of Class I, II and IIIA liquids may be stored outside of fire-resistant cabinets for each 100 ft² of space defined by fire-resistant walls/doors. Up to 2 gallons of Class I, II, and IIIA liquids may be stored in safety cans and safety cabinets for each 100 ft². These amounts may be doubled if there is an automatic fire suppression system (e.g. sprinklers). 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 of a highly volatile solvent such as isopentane, stored in glass has about the same ignitability risk as 2 gallons stored in safety cans. Safety cans should be used instead of glass bottles if the purity required does not mandate glass storage.

REFERENCES

GEN.76600  Volatile Solvent Ventilation  Phase II

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

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

REFERENCES

GEN.76700  Acid/Base Storage  Phase II

Supplies of concentrated acids and bases are stored in cabinets near floor level.

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

COMPRESSED GASES

Inspector Instructions:

- Gas cylinders (properly stored and secured)

GEN.76800  Gas Cylinder Storage  Phase II

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

REFERENCES

GEN.76900  Gas Cylinders Containing Flammable Gases  Phase I

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, reserved exclusively for that purpose, and which has a fire-resistance classification of at least two hours.
2. No more than one extra cylinder of compressed, flammable gas (other than those actually connected for use) at any one workstation. (Exception: small cylinders (e.g. propane) may aggregate to a 2-day working supply at the workstation.)
3. Cylinders are positioned well away from open flame or other heat sources, not in corridors and not within exhaust canopies.

REFERENCES

RADIATION SAFETY

TO DO: Type your text here...

Inspector Instructions:

- Sampling of radiation safety policies and procedures

GEN.77000  Radiation Safety Manual  Phase II

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

GEN.77100 Radioactive Material Handling Phase II

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

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

REFERENCES

ENVIRONMENTAL SAFETY

Inspector Instructions:

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

GEN.77200 Ergonomics Phase II

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

NOTE: The program may include training of employees about risk factors, identifying physical work activities or conditions of the job commonly associated with work-related MSDs, and recommendations for eliminating MSD hazards. Laboratory activity, workplace and equipment (e.g. chairs, laboratory workstations, computer keyboards, and displays) should be designed to reduce the risks of ergonomic distress disorders and accidents.
Evidence of Compliance:
✓ Records of ergonomic evaluation including recommendations for eliminating MSD hazards and appropriate corrective action based on assessment findings

REFERENCES
2) U.S. Dept. of Labor, Occupational Safety and Health Administration. Ergonomic safety and health program management guideline. 54 Fed Register 3904 (1989), modified at 29CFR1910

GEN.77300 Excessive Noise

Phase I

The laboratory has a policy to protect personnel from excessive noise levels.

NOTE: The laboratory should provide protection against the effects of noise exposure when sound levels equal or exceed an 8-hour time-weighted average sound level of 85 decibels. The laboratory should monitor noise exposure if there is an indication that excessive noise levels are present (for example, when noise levels exceed 85 decibels, people have to shout to be heard).

REFERENCES

**REVISED** 06/17/2010
GEN.77400 Emergency Eyewash

Phase II

The laboratory has adequate plumbed or self-contained emergency eyewash facilities in every area where there are hazardous chemicals as defined by the laboratory's chemical hygiene plan (e.g. chemicals that are irritating, corrosive, toxic by contact or absorption, etc.).

NOTE: The eyewash facility includes the following:

1. No greater than 10 seconds travel distance from areas in the laboratory where hazardous chemicals are present
2. Capable of delivering 1.5 liters/minute for 15 minutes
3. Flow is provided to both eyes simultaneously
4. Nozzles or covers to protect from airborne contaminants
5. Hands-free flow once activated
6. Signage for location of eyewash
7. Unobstructed path with unlocked doors opening in the direction of the eyewash
8. Plumbed systems are protected from unauthorized shut off
9. Tepid fluid temperature
10. Plumbed systems are activated weekly
11. Self-contained units are visually examined weekly

Evidence of Compliance:
✓ Records of testing the plumbed eyewash

REFERENCES

OTHER HAZARDS

Inspector Instructions:
Laboratory General Checklist

**GEN.77500**  **Liquid Nitrogen**  **Phase I**

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

**NOTE:** Procedures for the safe handling of liquid nitrogen include:

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

**REFERENCES**
1) OSHA Technical Link "Nitrogen" dated 4/27/1999  

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

**Policies are documented to prevent or reduce ultraviolet light exposure from instrument sources.**

**NOTE:** UV light may cause corneal or skin burns from direct or deflected light sources. Wherever UV light sources are used, suitable and adequate personal protective equipment must be provided, and appropriate approved signage displayed. Laboratories may obtain information on safety from manufacturers of devices that emit UV light.

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

**Evidence of Compliance:**
✓ Warning signage on source equipment **AND**
✓ Suitable PPE available, if required by the policy

**REFERENCES**
2) [http://www.cdc.gov/niosh/hcwold5e.html](http://www.cdc.gov/niosh/hcwold5e.html)

**GEN.77700**  **Latex Allergy**  **Phase I**

**The laboratory has a documented 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 workers from infectious materials.

2. Provision of education programs and training materials about latex allergy

3. Evaluation of current prevention and control strategies whenever a worker is diagnosed with latex allergy

Evidence of Compliance:
✓ Records of employee education/training on latex allergies AND
✓ Records of evaluation of the plan, when appropriate

REFERENCES

WASTE DISPOSAL

Inspector Instructions:

READ

- Sampling of waste disposal policies and procedures

ASK

- How does your laboratory dispose of sharps?
- How does your laboratory dispose of hazardous chemicals?

Hazardous Chemical Waste Disposal

Policies and procedures are documented and adequate for hazardous chemical waste disposal.

NOTE: 1. The laboratory is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition. 2. The method for the disposal of all solid and liquid wastes is in compliance with local, state and federal regulations. (Whether or not laboratory management is responsible for waste disposal, the laboratory should have documentation that the facility is in compliance with all applicable regulations. Prevailing local,
Laboratory General Checklist
07.11.2011

state and federal (EPA) regulations should be reviewed by the laboratory director, safety officer or hospital engineer to be sure that the laboratory is in compliance with regulations.

Evidence of Compliance:
✓ Records of review of regulations for compliance

REFERENCES

GEN.77900 Biohazard Disposal Containers
Phase II

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

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

REFERENCES

GEN.78000 Sharps Disposal
Phase II

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

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

REFERENCES