



*Advancing Excellence*

## COMMISSION ON LABORATORY ACCREDITATION

### Laboratory Accreditation Program

## LABORATORY GENERAL CHECKLIST

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# LABORATORY GENERAL

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**SUMMARY OF CHANGES**  
**LABORATORY GENERAL Checklist**  
9/27/2007 Edition

The following questions 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 questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

*Note: For revised checklist questions, 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 Questions**

<u>Question</u>	<u>Effective Date</u>
GEN.40108	09/27/2007
GEN.40116	09/27/2007
GEN.40938	09/27/2007
GEN.50057	09/27/2007
GEN.50614	09/27/2007
GEN.51171	09/27/2007
GEN.51728	09/27/2007
GEN.52285	09/27/2007
GEN.52842	09/27/2007
GEN.26791	10/31/2006
GEN.41307	10/31/2006
GEN.20365	04/06/2006
GEN.20374	04/06/2006
GEN.40508	04/06/2006
GEN.70824	04/06/2006
GEN.72075	04/06/2006

**REVISED Checklist Questions**

<u>Question</u>	<u>Effective Date</u>
GEN.20377	09/27/2007
GEN.26791	09/27/2007
GEN.40490	09/27/2007
GEN.41067	09/27/2007
GEN.41096	09/27/2007
GEN.41303	09/27/2007

GEN.41500	09/27/2007
GEN.41700	09/27/2007
GEN.42800	09/27/2007
GEN.43450	09/27/2007
GEN.44100	09/27/2007
GEN.55500	09/27/2007
GEN.72500	09/27/2007
GEN.20365	10/31/2006
GEN.20368	10/31/2006
GEN.20376	10/31/2006
GEN.40470	10/31/2006
GEN.40491	10/31/2006
GEN.40522	10/31/2006
GEN.41340	10/31/2006
GEN.54400	10/31/2006
GEN.20375	04/06/2006
GEN.41320	04/06/2006
GEN.53400	04/06/2006
GEN.71000	04/06/2006

**DELETED Checklist Questions**

<u>Question</u>	<u>Effective Date</u>
GEN.10500	09/27/2007
GEN.11484	09/27/2007
GEN.11742	09/27/2007
GEN.12000	09/27/2007
GEN.41650	09/27/2007
GEN.20332	10/31/2006
GEN.20370	10/31/2006
GEN.20380	10/31/2006
GEN.30200	10/31/2006
GEN.54450	10/31/2006
GEN.20369	04/06/2006
GEN.30050	04/06/2006

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## CONTINUING EDUCATION INFORMATION

Beginning January 2008, you may earn continuing education credits (CME/CE) by completing an online Inspection Preparation activity that includes review of this checklist.

Prior to reviewing the checklist, log on to the CAP Web site at [www.cap.org](http://www.cap.org) <<http://www.cap.org>>, click the Education Programs tab, then select Laboratory Accreditation Program (LAP) Education Activities, and Inspection Preparation for complete instructions and enrollment information.

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**PARTICIPANTS ARE REMINDED THAT THE CONTENTS OF THIS CHECKLIST APPLY TO ALL SECTIONS OF THE LABORATORY. INSPECTION OF A DISCIPLINE-SPECIFIC AREA (e.g., ANATOMIC PATHOLOGY) IS NOT LIMITED TO THE CONTENTS OF THE DISCIPLINE-SPECIFIC CHECKLIST, BUT INCLUDES ALL APPLICABLE PORTIONS OF THIS LABORATORY GENERAL CHECKLIST. ALL SECTIONS OF THE LABORATORY MUST BE FAMILIAR WITH THESE CONTENTS.**

### ***NOTE on CAP PATIENT SAFETY GOALS:***

*CAP has developed a core set of laboratory patient safety goals for pre- and post-analytic laboratory processes. These goals are:*

1. *Improve patient and sample identification*
  - a. *At the time of specimen collection*
  - b. *At the time of analysis*
  - c. *At the time of results delivery*
2. *Improve the verification and communication of life threatening or life altering information regarding*
  - a. *Malignancies*
  - b. *HIV and other infections*
  - c. *Cytogenetic abnormalities*
  - d. *Critical results*
3. *Improve the identification, communication and correction of errors*
4. *Improve coordination of the laboratory patient safety role within healthcare organizations (nursing, administration, POCT personnel, providers)*

*The checklists contain multiple questions that deal with the above goals. Laboratories should emphasize these goals in their quality management activities. Approaches include monitoring activities related to the goals (for example, number of mislabeled specimen containers), with corrective/preventive action as necessary; investigation of sentinel events, with corrective/preventive action as necessary; and evaluation and revision of processes and procedures affecting the goals, to optimize laboratory performance. The laboratory should document how it addresses these goals.*

*The inspector should pay particular attention to checklist questions that address the above patient safety goals, and communicate any findings to the inspection team leader, who will address patient safety goal issues with the laboratory director.*

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## **INSPECTION TECHNIQUES – KEY POINTS**

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**I. READ – OBSERVE – ASK** – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

### **READ = Review of Records and Documents**

Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

### **OBSERVE – ASK = Direct Observation and Asking Questions**

Observing and asking questions accomplish the following:

1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed
3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.
- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you've seen and observations you've made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.

- Ask open-ended questions that start with phrases such as “show me how...” or “tell me about...” or “what would you do if...”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the lab’s procedures and policies, and give you a feel for the general level of performance of the laboratory.
- Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when control results exceed defined tolerance limits?” ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be, “What would you do if you could not identify an obvious cause for the change in SD or CV?”

## II. Evaluate Selected Specimens and Tests in Detail

**For the Laboratory General Checklist: Follow a specimen through the laboratory.** By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical results and revisions to reports.

**For the individual laboratory sections:** Consult the laboratory’s activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

*To evaluate preanalytic and postanalytic issues:* Choose a representative specimen and “follow” the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

*To evaluate analytic processes:* Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

**III. Verify that proficiency testing problem have been resolved:** From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough

when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

**IV. Review correction of previous deficiencies:** Review the list of deficiencies from the previous on-site inspection provided in the inspector’s packet. Ensure that they have been appropriately addressed.

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**PROFICIENCY TESTING**

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Definitions:

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory’s results with those of other laboratories in the group and/or with an assigned value...(adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at <http://www.nccls.org/>).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT--for example, split-sample testing, testing by a different method, etc.

GEN.10000

Phase II

N/A YES NO

**Does the laboratory have written procedures for proficiency testing sufficient for the extent and complexity of testing done in the laboratory?**

*NOTE: The laboratory must have written procedures for the proper handling, analysis, review and reporting of proficiency testing materials. There must be written procedure(s) for investigation and correction of problems that are identified by unacceptable proficiency testing results. The laboratory should also have procedure(s) for investigation of results that, although acceptable, show bias or trends suggesting a problem.*

*CAP-accredited laboratories must participate in proficiency testing (PT) (when available through CAP or a CAP-approved alternate provider) for all patient tests designated by CAP. The current list of analytes for which CAP requires PT is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1.*

*The CAP office audits PT participation to assure that accredited laboratories participate in PT as appropriate.*

COMMENTARY:



N/A

**GEN.11226****Phase II****N/A YES NO**

**Does the laboratory have a procedure for assessing its performance on PT challenges that were intended to be graded, but were not?**

*NOTE: This question addresses PT challenges that were intended to be graded, but were not, for reasons such as: 1) the laboratory submitted its results after the cut-off date, 2) the laboratory did not submit results, 3) the laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). Also, if possible, the laboratory should assess its performance on PT challenges that were not graded because of lack of consensus. For guidance on the approach to these situations, refer to appendix I in the CAP Laboratory Accreditation Manual ([http://www.cap.org/apps/docs/laboratory\\_accreditation/checklists/checklist\\_reference\\_links.doc](http://www.cap.org/apps/docs/laboratory_accreditation/checklists/checklist_reference_links.doc)).*

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3705 [42CFR493.1236(a)(2)].

**GEN.12258****Phase II****N/A YES NO**

**Is there a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider?**

*NOTE: Under CLIA-88 regulations, there is a strict prohibition against interlaboratory communications about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider. The laboratory director is responsible for enforcing this prohibition.*

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)(3)]; 2) Bierig JR. Comparing PT results can put a lab's CLIA license on the line. Northfield, IL: College of American Pathologists *CAP Today*. 2002;16(2):84-87.

**GEN.13032**

**Phase II**

**N/A YES NO**

**Is there a policy that prohibits referral of proficiency testing specimens to another laboratory?**

*NOTE: Under CLIA-88 regulations, there is a strict prohibition against referring proficiency testing specimens to another laboratory. In other words, the laboratory may not refer a proficiency testing specimen to a laboratory with a different CLIA number (even if the second laboratory is in the same health care system). It is the responsibility of the laboratory director to ensure that this prohibition is enforced.*

*This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens. For example, a laboratory’s routine procedure for review of abnormal blood smears might be referral of the smear to a pathologist located at another site (i.e., with a different CLIA number than the referring laboratory). For proficiency testing specimens, the referring laboratory must NOT follow its routine procedure in this situation. Rather, the laboratory must submit a PT result of “test not performed” since the review does not occur within the referring laboratory.*

**COMMENTARY:**

N/A

**REFERENCE:** Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28): [42CFR493.801(b)(4)].

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**QUALITY MANAGEMENT**

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*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.*

**GEN.13806**

**Phase II**

**N/A YES NO**

**Does the laboratory have 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, GP-22, or GP-26; the ISO 9000 series or ISO 15189:2003; AABB's quality program; CAP's quality management publications; or it may be of the laboratory's own design.*

## COMMENTARY:

N/A

REFERENCES: 1) Joint Commission on Accreditation of Healthcare Organizations. Using Performance Improvement Tools in Health Care Settings, Third Edition. Oakbrook Terrace, IL: JCAHO, 2006; 2) ISO Standards compendium: ISO 9001:2000, Quality management systems -- Requirements. Geneva, Switzerland: International Organization for Standardization, 2000; 3) ISO 15189:2003 Medical laboratories -- Particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2003; 4) NCCLS. *A Quality Management System Model for Health Care; Approved Guideline—Second Edition*. NCCLS document HS1-A2 (ISBN 1-56238-554-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 5) NCCLS. *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition*. NCCLS document GP22-A2 (ISBN 1-56238-552-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 6) NCCLS. *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition*. NCCLS document GP26-A3 (ISBN 1-56238-553-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 7) Nakhleh RE, Fitzgibbons PL. *Quality Management in Anatomic Pathology*. Chicago, IL: CAP Press, 2005; 8) Valenstein P. *Quality Management In Clinical Laboratories*. Chicago, IL: CAP Press, 2005; 9) Berte L. *Quality Manual Preparation Workbook for Blood Banking*, 2nd edition. Bethesda, MD: AABB Press, 2005.

GEN.15354

Phase II

N/A YES NO

**If the laboratory is located within a larger health care institution, is the laboratory QM program coordinated with other programs in the facility by an individual qualified as a laboratory director?**

*NOTE: Evidence of program coordination consists of either (1) periodic reporting of laboratory QM performance to another department or an organizational quality committee outside the laboratory, or (2) joint development of a QM initiative with medical staff in another department or nursing staff.*

*This question does not apply to independent, referral laboratories. It applies only to those laboratories where laboratory medicine and direct patient care are integrated.*

## COMMENTARY:

N/A

**GEN.16902****Phase II****N/A YES NO****For laboratories that have been CAP accredited for more than 12 months, has the QM plan been implemented as designed?**

*NOTE: Evidence that the plan has been implemented as designed requires all of the following: (1) quality measurements/assessments specified in the plan are being substantially carried out; (2) there is evidence of active review of quality measurements; (3) if target performance levels are specified in the plan and the targets are not being met, there is documented follow-up action; (4) any interventions/changes to operations that are specified in the plan has been carried out as scheduled, or the reason for delay documented; and (5) any communication of information that is required by the plan has taken place.*

COMMENTARY:

N/A

**GEN.20100****Phase II****N/A YES NO****Does the QM program cover 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.*

COMMENTARY:

N/A

**GEN.20208****Phase II****N/A YES NO****Does the QM system include a program to identify and correct 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.*

## COMMENTARY:

N/A

REFERENCES: 1) Richter ED, Barach P. Occupation and environment in internal medicine: sentinel events and trigger questions. *Mt Sinai J Med.* 1995;62:390-400; 2) Spath PL. How to conduct a thorough sentinel event investigation. *J Healthcare Risk Mgmt.* 1998;18(4):5-6; 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1233]; 4) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003 (4.8).

GEN.20262

Phase I

N/A YES NO

**Does the QM program include review of errors, complaints, and incidents at defined intervals to identify trends and initiate corrective/preventive actions as appropriate?**

*NOTE: Compliance with this requirement can be assessed using a representative sample. Errors, complaints, or incidents should be examined to determine whether they (1) were investigated and corrected as applicable; (2) were analyzed periodically in groups to detect recurring patterns or trends; and (3) that recurring patterns of incidents (if any) were addressed systematically. In addition, for any incident that constitutes a “sentinel event” (patient death or serious physical or psychological injury or risk thereof) a root cause analysis must be conducted and action plan implemented to address root causes.*

## COMMENTARY:

N/A

REFERENCES: 1) Richter ED, Barach P. Occupation and environment in internal medicine: sentinel events and trigger questions. *Mt Sinai J Med.* 1995;62:390-400; 2) Spath PL. How to conduct a thorough sentinel event investigation. *J Healthcare Risk Mgmt.* 1998;18(4):5-6; 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1233]; 4) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003 (4.8).

GEN.20316

Phase II

N/A YES NO

**Does the QM program include monitoring key indicators of quality?**

*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*
- 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 reissue.*
- 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 25<sup>th</sup> 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.*

## COMMENTARY:

N/A

REFERENCES: 1) Clinical Laboratory Improvement Amendments 42 CFR § 493.1701; 2) Howanitz PJ, *et al.* Continuous wristband monitoring over 2 years decreases identification errors: a College of American Pathologists Q-Tracks Study. *Arch Pathol Lab Med.* 2002; 126:809-815; 3) Valenstein PN, *et al.* Ordering accuracy. A College of American Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med.* 1995; 119:117-122; 4) Novis DA, *et al.* Biochemical markers of myocardial injury test turnaround time. *Arch Pathol Lab Med.* 2004; 128:158-164; 5) Howanitz PJ, *et al.* Laboratory critical values policies and procedures. *Arch Pathol Lab Med.* 2002; 126:663-669; 6) Zarbo RJ, *et al.* Customer satisfaction in anatomic pathology. *Arch Pathol Lab Med.* 2003; 127:23-29; 7) Jones BA, *et al.* Chemistry specimen acceptability: a College of American Pathologists Q-Probes study of 453 laboratories. *Arch Pathol Lab Med.* 1997; 121:19-26; 8) Nakhleh RE, *et al.* Amended reports in surgical pathology and implications for diagnostic error detection and avoidance. *Arch Pathol Lab Med.* 1998; 122:303-309; 9) Nakhleh RE, *et al.* Surgical pathology specimen identification and accessioning: A College of American Pathologists Q-Probes Study of 1,004,115 cases from 417 institutions. *Arch Pathol Lab Med.* 1996; 120:227-233; 10) Novis DA, *et al.* Quality indicators of fresh frozen plasma and platelet utilization. *Arch Pathol Lab Med.* 2002; 126:527-532; 11) Schiffman RB, *et al.* Blood culture contamination. *Arch Pathol Lab Med.* 1998; 122:216-21; 12) Bonini P, *et al.* Errors in laboratory medicine. *Clin Chem.* 2002, 48:691-698.

GEN.20348

Phase II

N/A YES NO

**Are preanalytic processes monitored?**

*NOTE: Preanalytic (i.e., pre-examination) variables include all steps in the process prior to the analytic phase of testing, starting with the physician's order. Examples include accuracy of transmission of physicians' orders, specimen transport and preparation, requisition accuracy, quality of phlebotomy services, specimen acceptability rates, etc. The variables chosen should be appropriate to the laboratory's scope of care.*

## COMMENTARY:

N/A

REFERENCES: 1) Dale JC, Howanitz PJ. Patient satisfaction with phlebotomy. *Lab Med.* 1996;27:188-192; 2) Dale JC, *et al.* Early morning blood collections. A College of American Pathologists Q-Probes study of 657 institutions. *Arch Pathol Lab Med.* 1998;122:865-870; 3) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150; 4) Narayanan S. The preanalytic phase. An important component of laboratory medicine. *Am J Clin Pathol.* 2000;113:429-452; 5) Tarapchak P. Identify, eliminate the 'error' of your ways. *Advance/Lab.* 2000;9(3):64-71; 6) Eggert AA, *et al.* Using detailed computer tracking to monitor and improve

outpatient phlebotomy service and overall test turn-around time. *Clin Chem.* 2000;46:A71; 7) Zhang MM, *et al.* Outpatient expectations and satisfaction with phlebotomy: measurement after massive consolidation. *Clin Chem.* 2000;46:A72; 8) Wang TY, *et al.* Specimen stability in routine hematology and chemistry panel. A study to further define possible changes in laboratory parameters due to storage conditions. *Clin Chem.* 2000;46:A144; 9) Galloway M, Nadin L. Benchmarking and the clinical laboratory. *J Clin Pathol.* 2001;54:590-597; 10) Emerson JF, Emerson SS. The impact of requisition design on laboratory utilization. *Am J Clin Pathol.* 2001;116:879-884; 11) Assessment of sweat-testing practices for the diagnosis of cystic fibrosis. *Arch Pathol Lab Med.* 2001;125:1420-1424; 12) Bonini P, *et al.* Errors in laboratory medicine. *Clin Chem.* 2002;48:691-698; 13) Dale JC, Novis DA. Outpatient phlebotomy success and reasons for specimen rejection. A Q-Probes study. *Arch Pathol Lab Med.* 2002;126:416-419; 14) Howanitz PJ, *et al.* Continuous wristband monitoring over 2 years decreases identification errors. A College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2002;126:809-815; 15) NCCLS. Routine urinalysis and collection, transportation, and preservation of urine specimens – second edition; approved guideline GP16-A2. Wayne, PA: NCCLS, 2001.

**GEN.20364****Phase II****N/A YES NO****Are postanalytic processes monitored?**

*NOTE: Postanalytic (i.e., post-examination) variables include all steps in the overall laboratory process between completion of the analytic phase of testing and results receipt by the requesting physician. Examples are accuracy of data transmission across electronic interfaces, reflex testing, turnaround time from test completion to chart posting (paper and/or electronic), and interpretability of reports. This list is neither all-inclusive nor exclusive, providing the variables chosen are appropriate to the laboratory's scope of care.*

COMMENTARY:

N/A

REFERENCES: 1) Novis DA, Dale JC. Morning rounds inpatient test availability. A College of American Pathologists Q-Probes study of 79 860 morning complete blood cell count and electrolyte test results in 367 institutions. *Arch Pathol Lab Med.* 2000;124:499-503; 2) Howanitz PJ, Cembrowski GS. Postanalytical quality improvement. A College of American Pathologists Q-Probes study of elevated calcium results in 525 institutions. *Arch Pathol Lab Med.* 2000;124:504-510; 3) Howanitz JH, Howanitz PJ. Timeliness as a quality attribute and strategy. *Am J Clin Pathol.* 2001;116:311-315; 4) Jones BA, Novis DA. Nongynecologic cytology turnaround time. A College of American Pathologists Q-Probes study of 180 laboratories. *Arch Pathol Lab Med.* 2001;125:1279-1284; 5) Steindel SJ, Jones BA. Routine outpatient laboratory test turnaround times and practice patterns. A College of American Pathologists Q-Probes study. *Arch Pathol Lab Med.* 2002;126:11-18.





*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#.*

COMMENTARY:

N/A

**\*\*REVISED\*\***      **10/31/2006**

**GEN.20368**      **Phase II**      **N/A YES NO**

**Have referring physicians' or patients' satisfaction with laboratory service been measured within the past 2 years?**

*NOTE: Indicators of physician satisfaction may include (1) formal surveys, (2) referral statistics, and or (3) complaint rates. For patients, satisfaction with the phlebotomy service may be measured.*

COMMENTARY:

N/A

REFERENCES: 1) So you're going to collect a blood specimen. An introduction to phlebotomy, 7th edition. Northfield, IL: College of American Pathologists, 1996; 2) Steindel SJ, Howanitz PJ. Physician satisfaction and emergency department laboratory test turnaround time. Observations based on College of American Pathologists Q-Probes studies. *Arch Pathol Lab Med.* 2001;125:863-871.

**GEN.20369**      **Phase II**      **N/A YES NO**

**Is the QM program appraised at least annually for effectiveness?**

*NOTE: There must be documentation that the laboratory director or designee(s) reviews the program at least annually. Appraisal of program effectiveness may be evidenced by an annual written QM report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.*

COMMENTARY:

N/A

GEN.20371

Phase I

N/A YES NO

**Does the laboratory have 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.*

*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>. 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.*

*Additional information is available on the FDA website, at <http://www.fda.gov/cdrh/mdr/index.html>, <http://www.fda.gov/cdrh/mdr/ndr/ndr-general.html>, [http://www.fda.gov/cdrh/postsurv/note\\_932700.html](http://www.fda.gov/cdrh/postsurv/note_932700.html) contains information on amendments to MDR requirements.*

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

COMMENTARY:

N/A

**GEN.20372          Phase I          N/A   YES   NO**

**Has the laboratory documented education of its personnel in the FDA procedure for voluntary reporting of device-related serious adverse patient events?**

*NOTE: FDA has a procedure for medical personnel to voluntarily report serious adverse patient events that may be related to a medical device (e.g., laboratory instruments, reagents or other accessory devices such as those used for phlebotomy or specimen collection). This procedure applies to adverse events noted spontaneously in the course of clinical care, not events that occur in the course of clinical trials or other studies. Information on how to submit a voluntary report is provided at <http://www.fda.gov/medwatch/report/hcp.htm>.*

*This checklist item does NOT apply to laboratories accredited under the CAP Forensic Drug Testing program.*

COMMENTARY:

N/A

**GEN.20373          Phase I          N/A   YES   NO**

**Does the laboratory report infectious organisms and other notifiable test results, as required by state and local authorities?**

*NOTE: The laboratory should have documentation indicating that it has reviewed state and local regulations regarding reporting of infectious organisms and other notifiable laboratory test results (e.g., blood lead levels). This documentation should include a listing of organisms and other test results that must be reported to authorities, and evidence that notifiable results have been reported.*

COMMENTARY:

N/A

**\*\*NEW\*\***                      **04/06/2006**

**GEN.20374**                      **Phase I**    **N/A YES NO**

**Does the laboratory have 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 questions 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.*

COMMENTARY:

N/A

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

**\*\*REVISED\*\***                      **04/06/2006**

**GEN.20375**                      **Phase II**    **N/A YES NO**

**Does the laboratory have a document control system?**

*NOTE: 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, or a designee who is qualified as a director, before implementation; 4, policies and procedures are reviewed at least annually 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 questions regarding procedure manuals are found in section-specific checklists, and in this checklist in the Collection Manual, Computer Services and Safety sections.*

COMMENTARY:

N/A

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 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003.

**\*\*REVISED\*\***      **10/31/2006**

**GEN.20376**      **Phase II**      **N/A YES NO**

**Are all quality management procedures, forms and records maintained under document control?**

COMMENTARY:

N/A

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 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003.

**\*\*REVISED\*\***      **09/27/2007**

**GEN.20377**

**Phase II**

**N/A YES NO**

**Are laboratory records and materials 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, whole blood, CSF, and body fluids (except urine) should be retained for 48 hours. Urine specimens should be retained for 24 hours. 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.*

*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 Hardware and 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, print-outs, 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, print-outs, 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.*

**COMMENTARY:**

N/A

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

GEN.23584

Phase II

N/A YES NO

**Has the laboratory conducted an interim self-inspection and documented efforts to correct deficiencies identified during that process?**

*NOTE: The interim self-evaluation inspection is an important aspect of continuing education and laboratory improvement. The use of a variety of mechanisms for self-evaluation (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.*

COMMENTARY:

N/A

\*\*NEW\*\* 10/31/2006

\*\*REVISED\*\* 09/27/2007

GEN.26791

Phase II

N/A YES NO

**Does the laboratory have 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 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*
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 prior to the change(s); or, in the case of unexpected changes, no later than 2 working days afterwards*

COMMENTARY:



N/A

**GEN.30000**

**Phase II**

**N/A YES NO**

**Is there 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).*

COMMENTARY:

N/A

**GEN.30070**

**Phase II**

**N/A YES NO**

**If the laboratory performs test procedures for which neither calibration nor control materials are available, have procedures been established to verify the reliability of patient test results?**

*NOTE: "Reliability" includes elements of accuracy, precision, and clinical discriminating power.*

COMMENTARY:

N/A

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**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.*

-----  
COLLECTION MANUAL AND OTHER DOCUMENTATION  
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GEN.40000      Phase II      N/A   YES   NO

**Is there a procedure manual or other source for the complete collection and handling instructions of all laboratory specimens?**

COMMENTARY:

N/A

REFERENCE: van Leeuwen AM. 6 Steps to building an efficiency tool. *Advance/Lab*. 1999;8(6):88-91.

GEN.40016      Phase II      N/A   YES   NO

**Is there documentation of at least annual review of the specimen collection/handling procedure manual by the current laboratory director or designee?**

COMMENTARY:

N/A

GEN.40032      Phase II      N/A   YES   NO

**Does the director or designee who meets CAP director qualifications review and approve all changes to the specimen collection/handling procedure manual before implementation?**

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

COMMENTARY:

N/A

GEN.40050      Phase II      N/A   YES   NO

**Is the specimen collection manual 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.*

COMMENTARY:

N/A

**GEN.40100**

**Phase II**

**N/A YES NO**

**Does the specimen collection manual include 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: The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report. 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. 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.).*

COMMENTARY:

N/A

REFERENCES: 1) Nakhleh RE, *et al.* Necessity of clinical information in surgical pathology. A College of American Pathologists Q-Probes study of 771 475 surgical pathology cases from 341 institutions. *Arch Pathol Lab Med.* 1999;123:615-619; 2) Burton JL, Stephenson TJ. Are clinicians failing to supply adequate information when requesting a histopathological investigation? *J Clin Pathol.* 2001;54:806-808; 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Fed Register.* 2003(Jan 24):3706 [42CFR493.1251(b)(1)].

**\*\*NEW\*\***      *09/27/2007***GEN.40108**      **Phase II**      **N/A YES NO****Are instructions provided for proper collection of timed urine specimens?**

COMMENTARY:

N/A

REFERENCE: NCCLS. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. NCCLS document GP16-A2 (ISBN 1-56238-448-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.**\*\*NEW\*\***      *09/27/2007***GEN.40116**      **Phase II**      **N/A YES NO****Are documented instructions provided for proper preservation and storage of urine when specimens are collected for special tests?***NOTE: This is particularly important for the collection of 24-hour urine specimens.*

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. NCCLS document GP16-A2 (ISBN 1-56238-448-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001; 2) Rafael J, *et al.* Is a preservative required for routine urinalysis? *Am J Clin Pathol.* 1997;108:344.**GEN.40125**      **Phase II**      **N/A YES NO****For specimens sent to reference laboratories, does the referring laboratory properly follow all requisition, collection and handling specifications of the reference laboratory?***NOTE: Preanalytic variables must be closely controlled to maintain specimen integrity. These include specimen temperature, transport time, and the interval before separation of blood cells from serum/plasma. 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. 24-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.).

## COMMENTARY:

N/A

REFERENCES: 1) Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-115; 2) Narayanan S. The preanalytic phase. An important component of laboratory medicine. *Am J Clin Pathol.* 2000;113:429-452.

## PHLEBOTOMY

*Accurate and precise laboratory data depends on properly performed phlebotomy to obtain a high quality specimen. The inspector should observe a representative sampling of phlebotomy performed by laboratory employees. Also, phlebotomy activities by employees of the laboratory's parent organization may be evaluated, if requested by that entity as part of the accreditation process.*

**\*\*REVISED\*\***      **10/31/2006**

**GEN.40470**      **Phase II**      **N/A YES NO**

**Is there documentation that all personnel performing patient blood collection have been trained in the proper selection and use of equipment/supplies, and collection techniques?**

*NOTE: This includes phlebotomists at remote sites that are owned and operated by the laboratory. The inspector should observe specimen collection practices at one or more sites within the institution.*

## COMMENTARY:

N/A

REFERENCES: 1) Galena HJ. Complications occurring from diagnostic venipuncture. *J Fam Pract.* 1992;34:582-584; 2) Piton JD, Forstater AT. Recurrent asystole associated with vasovagal reaction during venipuncture. *J Emerg Med.* 1993;11:723-727; 3) Becan-McBride K, et al. Phlebotomy. Collection, professionalism, and QA. Chicago, IL: ASCP Press, 1993; 4) Strand CL, et al. Effect of iodophor versus iodine skin preparation on blood culture contamination rate. *JAMA.* 1993;269:1004-1006; 5) Spitalnic SJ, et al. The significance of changing needles when inoculating blood cultures; a meta-analysis. *Clin Infect Dis.* 1995;21:1103-1106; 6) Strasinger SK, di Lorenzo

MA. Phlebotomy workbook for the multiskilled healthcare professional. Philadelphia: FA Davis, 1996; 7) So you're going to collect a blood specimen. An introduction to phlebotomy. 7th edition. Northfield, IL: College of American Pathologists, 1996; 8) Gibb AP, *et al.* Reduction in blood culture contamination rate by feedback to phlebotomists. *Arch Pathol Lab Med.* 1997;121:50-507; 9) Klosinki DD. Collecting specimens from the elderly patient. *Lab Med.* 1997;28:518-522; 10) Brigden ML, *et al.* Prothrombin time determination: the lack of need for a discard tube and 24-hour stability. *Am J Clin Pathol.* 1997;108:422-426; 11) NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 12) Larsson BA, *et al.* Venipuncture is more effective and less painful than heel lancing for blood tests in neonates. *Pediatrics.* 1998;101:882-886; 13) Berns SD, Matchett JL. Effect of phlebotomy technique on serum bicarbonate values. *Acad Emerg Med.* 1998;5(1):40-44; 14) Adcock DM, *et al.* Minimum specimen volume requirements for routine coagulation testing. Dependence on citrate concentration. *Am J Clin Pathol.* 1998;109:595-599; 15) Reneke J, *et al.* Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/l (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757; 16) Phelan S. Phlebotomy: review guide. Chicago, IL: ASCP Press, 1998; 17) Dale JC. Preanalytic variables in laboratory testing. *Lab Med.* 1998;29:540-545; 18) Dale JC, *et al.* Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615; 19) Pruett S. Needle-stick safety for phlebotomists. *Lab Med.* 1998;29:754-760; 20) Dale JC, Hamrick HJ. Neonatal bilirubin testing practices. Reports from 312 laboratories enrolled in the College of American Pathologists Excel proficiency testing program. *Arch Pathol Lab Med.* 2000;124:1425-1428; 21) Burns ER, Yoshikawa N. Hemolysis in serum samples drawn by emergency department personnel versus laboratory phlebotomists. *Lab Med.* 2002;33:378-380.

**\*\*REVISED\*\***      **09/27/2007**

**GEN.40490**      **Phase II**      **N/A YES NO**

**Does the individual collecting the specimen positively identify 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. When possible, the patient's identity should be verified by asking the patient to identify him- or herself. 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 question is to ensure a documented, consistently followed system for correct patient sample identification at the point of collection.*

COMMENTARY:

N/A

REFERENCES: 1) Garza D, Becan-McBride K. *Phlebotomy handbook*, 2nd ed. Norwalk, CT: Appleton & Lange, 1989; 2) Renner SW, *et al.* Wristband identification error reporting in 712 hospitals. A College of American Pathologists' Q-Probes study of quality issues in transfusion practice. *Arch Pathol Lab Med.* 1993;117:573-577; 3) So you're going to collect a blood specimen. An introduction to phlebotomy. 7th edition. Northfield, IL: College of American Pathologists, 1996; 4) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207; 5) NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 6) Howanitz PJ, *et al.* Continuous wristband monitoring over 2 years decreases identification errors. A College of American Pathologists Q-Tracks study. *Arch Pathol Lab Med.* 2002;126:809-815.

**\*\*REVISED\*\***      **10/31/2006**

**GEN.40491**      **Phase II**      **N/A YES NO**

**Are specimens uniquely identified to minimize sample mixups, mislabeling, etc.?**

*NOTE: All specimens must be labeled at the time of collection to provide unique identification. Ideally, a name-number system is desirable so there are at least two separate identifying items on each sample; this is specifically required by the transfusion medicine laboratory for samples submitted for compatibility testing, and by the reproductive laboratory for andrology and embryology specimens.*

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition.* NCCLS document H1-A5 (ISBN 1-56238-519-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 2) So you're going to collect a blood specimen. An introduction to phlebotomy, 7th edition. Northfield, IL: College of American Pathologists, 1996; 3) NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition.* NCCLS document H3-A5 (ISBN 1-56238-515-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003; 4) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard--Second Edition.* CLSI document AUTO2-A2 (ISBN 1-56238-589-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**GEN.40492**      **Phase I**      **N/A YES NO**

**Does the laboratory have 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 cerebrospinal fluid, etc.). 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.*

## COMMENTARY:

N/A

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

**GEN.40493****Phase II****N/A YES NO**

**Are all blood samples used for compatibility testing 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. Labeling elements must include the patient's first and last name, unique identification number, and date of collection.*

## COMMENTARY:

N/A

REFERENCES: 1) Wenz B, *et al.* Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16; 2) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207.

**GEN.40496****Phase II****N/A YES NO**

**If the specimen label does not have the initials or other identifier of the phlebotomist, is there 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.*



COMMENTARY:

N/A

**GEN.40497**

**Phase II**

**N/A YES NO**

**If the laboratory collects specimens for paternity/forensic identity testing, are the following data 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.*

COMMENTARY:

N/A

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

**GEN.40498**

**Phase II**

**N/A YES NO**

**For paternity/forensic identity testing, is the information about each individual and the accuracy of the sample label verified by that individual or the legal guardian?**

COMMENTARY:

N/A

**GEN.40500**

**Phase I**

**N/A YES NO**

**Has the laboratory reviewed its specimen collection manual and phlebotomy practices to minimize unnecessarily large blood draw volumes?**

*NOTE: Blood losses from phlebotomy, particularly in pediatric patients and those with many venipunctures, may be a cause of iatrogenic anemia and increased transfusion needs. Adverse consequences of excess venipunctures include complications during collection for patients and health-care workers, hazards from subsequent transfusions, contending with increased amounts of hazardous waste, and greater cost. Suggested solutions include carefully considering the need for laboratory tests, avoiding unnecessary repetition of tests, and minimizing use of standing orders.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Buckley-Sharp MD. Anemia of investigation. *Lancet*. 1971;1:916; 2) Eyster E, Bernene J. Nosocomial anemia. *JAMA*. 1973;223:73-74; 3) Miller ES. Blood lost because of phlebotomy. *N Engl J Med*. 1975;292:319; 4) Lanuza DM, Jennrich JA. The amount of blood withdrawn for diagnostic tests in critically ill patients. *Heart Lung*. 1976;5:933-938; 5) Nexo E, et al. Volume of blood removed for analytical purposes during hospitalization of low-birthweight infants. *Clin Chem*. 1981;27:759-761; 6) Hashimoto F. Bleeding less for diagnostics. *JAMA*. 1982;248:171; 7) Smoller BR, Kruskal MS. Phlebotomy for diagnostic tests in adults. Pattern of use and effect on transfusion requirements. *N Engl J Med*. 1986;314:1233-1235; 8) Smoller BR, et al. Reducing adult phlebotomy blood loss with the use of pediatric-sized blood collection tubes. *Am J Clin Pathol*. 1989;91:701-703; 9) Dale JC, Pruett SK. Phlebotomy-a minimalistic approach. *Mayo Clin Proc*. 1993;68:249-255; 10) Zimmerman JE, et al. Evaluating laboratory usage in the intensive care unit: patients and institutional characteristics that influence frequency of blood sampling. *Crit Care Med*. 1997;25:737-748; 11) VanNewkirk LE, et al. Impact of reducing blood sample size on the incidence of transfusion in a neonatal ICU. *Lab Med*. 1998;29:306-310.

**GEN.40505**

**Phase I**

**N/A YES NO**

**Is there a mechanism to provide feedback to phlebotomists on issues relating to specimen quality?**

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

**COMMENTARY:**

N/A

**\*\*NEW\*\***

**04/06/2006**

**GEN.40508**

**Phase I**

**N/A YES NO**

**Does the laboratory have procedures to care for patients who experience adverse reactions from phlebotomy?**

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

COMMENTARY:

N/A

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TRANSPORT SERVICES

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*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.*

**GEN.40511**

**Phase II**

**N/A YES NO**

**Are all specimens properly packaged and labeled to indicate the general nature of the materials transported?**

*NOTE: All specimens must be properly packaged and labeled to indicate the general nature of the materials transported.*

COMMENTARY:

N/A

REFERENCES: 1) World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997; 2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication. General. Washington, DC: US Government Printing Office, 1998(Oct 1): [49CFR172]; 3) Beckala HR. Regulations for packaging and shipping laboratory

specimens. *Lab Med.* 1999;30:663-667; 4) Tarapchak P. In 'shipping' shape. *Advance/Lab.* 2000;9(7):48-59.

**GEN.40512****Phase II****N/A YES NO**

**Does the laboratory package and ship infectious material in accordance with applicable federal, state and local regulations?**

COMMENTARY:

N/A

REFERENCES: 1) World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997; 2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication. General. Washington, DC: US Government Printing Office, 1998(Oct 1): [49CFR172]; 3) Beckala HR. Regulations for packaging and shipping laboratory specimens. *Lab Med.* 1999;30:663-667; 4) Tarapchak P. In 'shipping' shape. *Advance/Lab.* 2000;9(7):48-59; 5) Snyder JW. Packaging and Shipping of Infectious Substances. *Clinical Microbiology Newsletter* 24(12):89-93, June 2002.

**GEN.40515****Phase II****N/A YES NO**

**Are transport personnel trained in appropriate safety and packaging procedures suitable to specimen type and distances transported?**

*NOTE: This 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.*

COMMENTARY:

N/A

REFERENCES: 1) World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control. Guidelines for the safe transport of infectious substances and diagnostic specimens. Geneva, Switzerland: WHO/EMC/97.3, 1997; 2) Department of Transportation. Research and Special Programs Administration. Hazardous materials table, special provisions, hazardous materials communication. General. Washington, DC: US Government Printing Office, 1998(Oct 1): [49CFR172]; 3) Beckala HR. Regulations for packaging and shipping laboratory specimens. *Lab Med.* 1999;30:663-66; 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\*\***      **10/31/2006**

**GEN.40522**      **Phase II**      **N/A YES NO**

**Is there documented certified training of all personnel involved in the packaging and shipping of infectious materials?**

*NOTE: Federal and international regulations mandate the proper packaging and transportation of infectious substances, also termed "etiologic agents." Infectious materials are now classified into two categories, category A (referred to as "infectious substances") and category B (referred to as "biologic substances, Category B"). Category A substances are capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Category B substances are not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Several examples of category A substances include organisms such as Brucella abortus (cultures only), Ebola virus, or Mycobacterium tuberculosis (cultures only). Most laboratory specimens fall under category B. Refer to the references below for further information.*

*Specific requirements are set forth by the U.S. Public Health Service, the U.S. International Air Transport Association (IATA), the U.S. Department of Transportation and the U.S. Postal Service. These apply to domestic transportation by land, air or sea, and to international air transportation. All personnel who package specimens for shipment must satisfactorily complete certified training in these requirements. Certified training is required every 2 years.*

*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).*

**COMMENTARY:**

N/A

**REFERENCES:** 1) <http://www.iata.org/dangerousgoods/index>; 2) <http://www.phppo.cdc.gov/nltm/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](http://hazmat.dot.gov/training/Transporting_Infectious_Substances_Safely.pdf).

**GEN.40530**      **Phase I**      **N/A YES NO**

**For specimens submitted to the laboratory from remote sites, is there 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 question applies to couriers/transportation systems that are part of the laboratory organization, not to outside courier systems.*

COMMENTARY:

N/A

**GEN.40535 Phase I N/A YES NO**

**Is there an adequate process for correcting problems identified in specimen transportation, and improving performance of clients or offices that frequently submit specimens improperly?**

COMMENTARY:

N/A

**GEN.40540 Phase I N/A YES NO**

**Is there a documented system to monitor the quality of specimens received from remote sites and collection sites not under the control of the laboratory?**

COMMENTARY:

N/A

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REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/ASSESSMENT  
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**GEN.40550 Phase II N/A YES NO**

**Is an appropriate specimen identification and accessioning system in use and consistently applied?**

COMMENTARY:

N/A



Pathologists Q-Probes study of 577 institutions. *Arch Pathol Lab Med.* 1995;119:117-122; 3)  
 Valenstein P, Meier F. Outpatient order accuracy. A College of American Pathologists Q-Probes study  
 of requisition order entry accuracy in 660 institutions. *Arch Pathol Lab Med.* 1999;123:1145-1150.

**GEN.40825 Phase II N/A YES NO**

**Is there 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.*

COMMENTARY:

N/A

REFERENCE: Clinical and Laboratory Standards Institute (CLSI). *Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard--Second Edition.* CLSI document AUTO2-A2 (ISBN 1-56238-589-5). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**GEN.40900 Phase II N/A YES NO**

**Is the date (and time, if appropriate) that the specimen was received by the laboratory recorded?**

COMMENTARY:

N/A

**GEN.40930 Phase I N/A YES NO**

**Does the laboratory have a mechanism to ensure that specimens are analyzed only at the request of an authorized person?**

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

COMMENTARY:



N/A

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

**GEN.40932****Phase II****N/A YES NO**

**For laboratories subject to CLIA-88 regulations, does the laboratory solicit 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 sheet.)*

COMMENTARY:

N/A

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

**GEN.40935****Phase I****N/A YES NO**

**Does the laboratory have a policy that personnel receiving verbal or phone orders read back the entire order to verify accuracy of transcription?**

COMMENTARY:

N/A



activator in collection container. *Clin Chem.* 1997;43:675-679; 13) Yared M, *et al.* Time dependent absorption of drugs by the barrier gel of the Greiner Vacuette blood collection tubes: impact on therapeutic drug monitoring. *Am J Clin Pathol.* 2000;114:302; 14) Frank E, *et al.* Effects of anticoagulants and collection containers on aluminum, copper, and zinc results. *Am J Clin Pathol.* 2000;114:313; 15) Gaillard C, Strauss F. Eliminating DNA loss and denaturation during storage in plastic microtubes. *Am Clin Lab.* 2001;20(2);52-5; 16) Salem RO, *et al.* Effect of specimen anticoagulant and storage on measurement of serum and plasma fatty acid ethyl ester concentrations. *Clin Chem.* 2001;47:126-127; 17) Kessler HH, *et al.* Effects of storage and types of blood collection tubes on hepatitis C virus level in whole blood samples. *J Clin Microbiol.* 2001;39:1788-179; 18) Hashim IA. Blood samples collected in serum-separator tubes give higher free tri-iodothyronine levels using the Immulite assay. *Clin Chem.* 2001;47(suppl):A14.

**GEN.40967                  Phase II    N/A   YES   NO**

**Are all centrifuges used in the specimen processing area clean and properly maintained?**

COMMENTARY:

N/A

**GEN.40992                  Phase II    N/A   YES   NO**

**Is there a documented protocol and schedule for maintenance of centrifuges (cleaning, changing brushes, *etc.*)?**

COMMENTARY:

N/A

**GEN.41017                  Phase II    N/A   YES   NO**

**Are the operating speeds of centrifuges checked periodically as needed for the intended use, and is this 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.*

COMMENTARY:

N/A

**GEN.41042**

**Phase II**

**N/A YES NO**

**Are refrigerator/freezer temperatures checked and recorded daily?**

*NOTE: This checklist question 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.*

**COMMENTARY:**

N/A

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**REPORTING OF RESULTS**

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*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.*

**\*\*REVISED\*\***      **09/27/2007**

**GEN.41067**

**Phase II**

**N/A YES NO**

**Does an individual meeting CAP laboratory director qualifications review and approve the content and format of paper and electronic patient reports at least annually?**

*NOTE 1: The laboratory director (or a designee who meets CAP qualifications for laboratory director) must review and, at least annually, approve the content and format of laboratory patient reports (whether paper or computer screen images) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff. This checklist question applies to paper and electronic medical records, including data displays in the laboratory information system and in information systems directly interfaced to the laboratory information system.*

*Best practice includes the thorough review and approval of tests at the time of implementation of a new report (or a new reporting mechanism such as a newly interfaced EMR system) and at the time of a major system change (either to the LIS or the receiving system). In addition, a sampling of test results must be assessed annually in the LIS and the receiving systems. Also, whenever a new test is implemented, sample results should be evaluated in both the LIS and the receiving systems.*

*NOTE 2: At times patients may bring laboratory results from outside laboratories to their physicians. The physicians may request that such results (or other test results from outside laboratories) be integrated into the laboratory information system. Whether or not to permit integration of outside results is at the discretion of the laboratory director. If such results are included in the LIS, they must include the name and address of the outside laboratory. Criteria for inclusion of such results in the LIS might include whether the quality of the outside laboratory has been evaluated by the laboratory director; CLIA licensure or equivalent; whether reference ranges differ from in-house tests; inclusion of units of measurement and reference range; and possession of an official report.*

*One option is to include such outside results in a section of the electronic medical record other than the laboratory database.*

COMMENTARY:

N/A

**\*\*REVISED\*\***      09/27/2007

**GEN.41096**      **Phase II**      **N/A YES NO**

**Does the paper or electronic report include the following elements?**

- 1. Name and address of testing laboratory (see note below)**
- 2. Patient name and identification number, or unique patient identifier**
- 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 directly interfaced to the laboratory information system. (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-88 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.*

*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.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3713 [42CFR493.1291(c)]; 2) Grasbeck R, Alstrom T, eds. Reference values in laboratory medicine. The current state of the art. New York: Wiley, 1981; 3) Statland BE. Clinical decision levels for lab tests. Oradell, NJ: Medical Economics Books; 4) Rochman H. Clinical pathology in the elderly. New York: Karger, 1988:207-216; 5) Tietz NW, ed. Clinical guide to laboratory tests. Philadelphia: WB Saunders, 1990; 6) NCCLS. How to define and determine reference intervals in the clinical laboratory; approved standard C28-A2. Wayne, PA: NCCLS, 2000.

**GEN.41250**

**Phase II**

**N/A YES NO**

**Are reports legible?**

**COMMENTARY:**

N/A

GEN.41300

Phase II

N/A YES NO

Are copies or files of reports 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.

COMMENTARY:

N/A

**\*\*REVISED\*\***      **09/27/2007**

GEN.41303

Phase II

N/A YES NO

Does the laboratory comply 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 periodically monitor compliance with HIPAA.

This checklist requirement applies only to laboratories subject to U.S. regulations.

COMMENTARY:

N/A

REFERENCE: Title 45 – Code of Federal Regulations – Parts 160, 162, and 164, Health Insurance Reform: Security Standards; Final Rule, *Federal Register*, Published Feb. 20, 2003, <http://www.cms.hhs.gov/SecurityStandard/Downloads/securityfinalrule.pdf>.

GEN.41304

Phase II

N/A YES NO

Is there a documented protocol in place to ensure that patient data are accessible only to those healthcare personnel who are authorized to review test results?

COMMENTARY:

N/A

**GEN.41306          Phase II**

**N/A   YES   NO**

**Is there 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.*

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7162 [42CFR493.1283(a)(4)].

**\*\*NEW\*\*                  10/31/2006**

**GEN.41307          Phase II**

**N/A   YES   NO**

**When errors are detected in patient test reports, does the laboratory promptly notify the responsible clinicians and issue a corrected report?**

COMMENTARY:

N/A

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

**GEN.41308          Phase II**

**N/A   YES   NO**

**Is there a documented system to ensure that all revised reports for previously reported incorrect (erroneous) patient results are identified as revised, corrected, or amended on all forms of patient reports (paper, video displays, etc.)?**

*NOTE: "Revised reports" means reports that contain any changes to patient results, accompanying reference intervals and interpretations, or patient identifiers, but not minor typographical errors of no*



*clinical consequence. Reports that display revised results must clearly indicate that the new result is a change from a previously reported result.*

COMMENTARY:

N/A

**GEN.41310          Phase II          N/A   YES   NO**

**When revised results are reported, are the revised and original data clearly identified as such, and are the original data readily accessible to the user for comparison?**

*NOTE: As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the 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). The precise format of corrected reports is at the discretion of the laboratory. Unless specifically endorsed by the medical staff/clients, it is not acceptable to simply indicate that a result has been revised, with the expectation that the reader will look up the previous result somewhere in the laboratory chart. 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 more appropriate than repeating the entire original report.*

COMMENTARY:

N/A

**GEN.41312          Phase I          N/A   YES   NO**

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

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

COMMENTARY:

N/A

GEN.41316

Phase I

N/A YES NO

**Is there 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.*

COMMENTARY:

N/A

\*\*REVISED\*\* 04/06/2006

GEN.41320

Phase II

N/A YES NO

**Does the laboratory have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when results of certain tests fall within established "alert" or "critical" ranges?**

*NOTE: Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. These results should be defined by the laboratory director, in consultation with the clinicians served.*

*Reference laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The reference laboratory should have a written agreement with the referring laboratory that indicates to whom the reference laboratory reports critical results.*

COMMENTARY:

N/A

REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA*. 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ*. 1993;25(3):22-27; 5) Tate KE, Gardner RM. Computers, quality, and the clinical laboratory: a look at critical values. Proc Annu Symp Comput

Appl Med Care. 1993;193-197; 6) Kaufman HW, Collins C. Notifying clients of life-threatening results. *Med Lab Observ.* 1994;26(8):44-45; 7) Emancipator K. Critical values. ASCP practice parameter. *Am J Clin Pathol.* 1997;108:247-253.

**GEN.41330****Phase II****N/A YES NO**

**Is there documentation of notification of the appropriate clinical individual of all critical results?**

*NOTE: Records must be maintained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records should include: date, time, responsible laboratory individual, person notified and test results. Any problem encountered in accomplishing this task should be investigated to prevent recurrence.*

*Reference laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The reference laboratory should have a written agreement with the referring laboratory that indicates to whom the reference laboratory reports critical results.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA.* 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ.* 1993;25(3):22-27; 5) Tate KE, Gardner RM. Computers, quality, and the clinical laboratory: a look at critical values. *Proc Annu Symp Comput Appl Med Care.* 1993;193-197; 6) Kaufman HW, Collins C. Notifying clients of life-threatening results. *Med Lab Observ.* 1994;26(8):44-45; 7) Emancipator K. Critical values. ASCP practice parameter. *Am J Clin Pathol.* 1997;108:247-253.

**\*\*REVISED\*\***      **10/31/2006**

**GEN.41340****Phase I****N/A YES NO**

**When critical results are communicated verbally or by phone, is there a policy that laboratory personnel ask for a verification “read-back” of the results?**

*NOTE: Laboratory personnel should document the read-back.*

*Transmission of critical results by electronic means (FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory should confirm receipt of the result by the intended recipient (e.g., by a phone call); however, no read-back is necessary.*

## COMMENTARY:

N/A

GEN.41345

Phase II

N/A YES NO

**Has the laboratory defined turnaround times (*i.e.*, the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and does it have 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.*

## COMMENTARY:

N/A

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

GEN.41350

Phase II

N/A YES NO

**Does the laboratory have a documented process for evaluating and selecting reference laboratories?**

*NOTE:*

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. *Laboratories subject to CLIA-88 must refer specimens for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.*
  
4. *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*

**COMMENTARY:**

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1034 [42CFR493.1242(c)]; 2) NCCLS. Selecting and evaluating a referral laboratory; approved guideline GP9-A. Wayne, PA: NCCLS, 1998; 3) Caro B. Department dollars. Planning a referral testing service program. *Advance/Lab*. 1999;8(4):22-24; 4) Brooks B. Cost considerations of esoteric testing. *Advance/Lab*. 1999;8(6):59-68; 5) Carter JE, Bennett B. Laboratory "send out" test review by pathology house staff: cost-cutting strategy. *Am J Clin Pathol*. 1999;112:572.

**GEN.41370                  Phase II    N/A    YES    NO**

**Is the laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), responsible for selecting referral laboratories?**

**COMMENTARY:**

N/A

**GEN.41430                  Phase II    N/A    YES    NO**

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

**COMMENTARY:**

N/A

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

GEN.41440

Phase II

N/A YES NO

**Are the essential elements of referred test results 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.*

COMMENTARY:

N/A

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

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### QUALITY OF WATER AND GLASSWARE WASHING

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**\*\*REVISED\*\***      **09/27/2007**

GEN.41500

Phase II

N/A YES NO

**Has the laboratory defined the specific type of water required for each of its testing procedures?**

*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 general 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.*

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

	CLRW
Maximum microbial content (CFU/mL)	10
Minimum resistivity (megohm-cm)	10 (in-line)
Particulate matter	0.22 $\mu$ m filter

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

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

The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked periodically. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Minimum monitoring for CLRW should include resistivity and microbiology cultures. Other criteria, such as pH, endotoxin/pyrogens, silicates and organic contaminants are at the discretion of the laboratory. 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.

#### COMMENTARY:

N/A

REFERENCES: 1) Gabler R, *et al.* Degradation of high-purity water on storage. *J Liquid Chromatogr.* 1983;6:2565-2570; 2) Mather J, *et al.* The effects of water purity and addition of common water contaminants on the growth of cells in serum-free media. *BioTechniques.* 1986;4:56-63; 3) Gould MJ. Evaluation of microbial/endotoxin contamination using the LAI test. *Ultrapure Water.* 1993;10:43-47; 4) Huang YH, *et al.* Comparison of Milli-Q PF Plus water to DEPC-treated water in the preparation and analysis of RNA. *BioTechniques.* 1995;19:656-661; 5) Paul DH. Ion exchange primer. *Ultrapure Water.* 1997;14:63-66; 6) Clinical and Laboratory Standards Institute (CLSI). *Preparation and Testing*

*of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition.* CLSI document C3-A4 (ISBN 1-56238-610-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 7) Srikanth B. Ultraviolet light: recent advancements in UV technology yield enhanced TOC reduction performance. *Ultrapure Water.* 1998;15:40-46; 8) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med.* 2000;31:605-611.

**GEN.41550**              **Phase II**    **N/A YES NO**

**Is there a documented statement of policies and procedures that defines the standards for, and frequency of testing water quality?**

COMMENTARY:

N/A

REFERENCES: 1) Clinical and Laboratory Standards Institute (CLSI). *Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition.* CLSI document C3-A4 (ISBN 1-56238-610-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 2) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med.* 2000;31:605-611.

**\*\*REVISED\*\***              **09/27/2007**

**GEN.41700**              **Phase II**    **N/A YES NO**

**Do records of water quality tests indicate that the water was tested for the specifications necessary for each intended use?**

*NOTE: Records of water quality testing must be complete and indicate that water meets the specifications listed in the table in the Note to the first checklist question in this section, above. In addition, testing for total organic carbon, silicates, and/or pyrogens must be documented if the laboratory finds that these contaminants adversely affect specific test methods.*

COMMENTARY:

N/A

REFERENCES: 1) Clinical and Laboratory Standards Institute (CLSI). *Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline—Fourth Edition.* CLSI document C3-A4 (ISBN 1-56238-610-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 2) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med.* 2000;31:605-611.



**GEN.41750          Phase II          N/A   YES   NO**

**Is there evidence of corrective action when water testing does not meet defined tolerance limits?**

COMMENTARY:

N/A

**GEN.41770          Phase II          N/A   YES   NO**

**Are there appropriate documented procedures for handling and cleaning glassware, including methods for testing for detergent removal?**

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

*The following test procedure is suitable for detecting detergent residues resulting from improper rinsing:*

- 1. Rinse a small clean beaker by filling and emptying 3 times with source water*
- 2. Fill a fourth time and measure pH using a pH meter. Record the pH as source water pH*
- 3. Take a piece of cleaned glassware you wish to test, fill about 10% full with source water. Use more water if necessary to get enough water to be able to sufficiently immerse the pH meter electrode*
- 4. Agitate water in glassware to extract residues from all possible surfaces*
- 5. Take pH reading with pH meter and record as glassware pH*
- 6. Any significant increase in pH indicates alkaline detergent residue. A significant change is 0.2 or more pH units on a pH meter measuring to 0.1 pH units of sensitivity. A result of less than 0.2 pH units change indicates properly rinsed glassware*

*If deionized water is used as the sample water, a slight amount of reagent grade, non-buffering salt (NaCl, CaCl<sub>2</sub>) should be added to the sample water to allow pH meter to function properly. To avoid contaminating clean glassware, dump the glassware testing solution into a triple rinsed beaker and then add the non-buffering salt before measuring the pH with a meter.*

*Detergents and surface-active agents can interfere with some pH paper by causing a decrease of several pH units in reading. Test any pH paper with these detergents to determine if there is any interference before adapting this procedure to use with pH paper. The laboratory should test approximately 1% of large frequently washed quantities of glassware and 5% of smaller quantities of less frequently washed glassware, and rotate the types of glassware tested. Narrow-necked volumetric flasks should be tested more frequently. The laboratory should keep records of the test date, types of glassware tested and test results.*

*Commercial kits for detection of anionic detergent residues are available.*

COMMENTARY:

N/A

REFERENCE: New York, NY: Alconox, Inc (<http://www.alconox.com>).

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**TEST METHOD VALIDATION**

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**METHOD PERFORMANCE SPECIFICATIONS**  
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NOTE: The subsection on METHOD PERFORMANCE SPECIFICATIONS does not apply to waived tests.

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*Sound laboratory practice requires full characterization of an assay before its use for patient testing, without regard to when the test was first introduced by a given laboratory. The laboratory must have data on each test's accuracy, precision, analytic sensitivity, interferences and reportable range (i.e., analytic measurement range (AMR) and clinically reportable range (CRR)) as applicable.*

*Laboratories subject to CLIA 88: For unmodified FDA-cleared or approved tests, the laboratory may use data from manufacturers' information or published reports, but the laboratory must verify outside data on accuracy, precision and reportable range. For tests that are not FDA-cleared or approved, or for FDA-cleared/approved tests modified by the laboratory, the laboratory must establish accuracy, precision, analytic sensitivity, interferences and reportable range, as applicable; data on interferences may be obtained from manufacturers or published literature, as applicable.*

*Laboratories not subject to CLIA 88: The laboratory must verify or establish analytic accuracy, precision, analytic sensitivity, analytic specificity (interfering substances) and reportable range for each test. Laboratories may use information from manufacturers, published literature, or studies performed in other laboratories, but should verify such outside information, whenever practical.*

*The laboratory must retain records of method performance specifications while the method is in use and for at least two years after discontinuation of a method.*

**GEN.42020****Phase II****N/A YES NO****Has the laboratory verified or established and documented analytic accuracy and precision for each test?**

*NOTE: Where current technology permits, accuracy is established by comparing results to a definitive or reference method, or may be verified by comparing results to an established comparative method. Use of reference materials or other materials with known concentrations or activities is suggested in establishing or verifying accuracy. Precision is established by repeat measurement of samples at varying concentrations or activities within-run and between-run over a period of time.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7164 [42CFR493.1253]; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):62607-62608 [42CFR493.1253]; 3) NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. NCCLS document EP9-A2 (ISBN 1-56238-472-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002; 4) Voss EM, *et al.* Determining acceptability of blood glucose meters. Statistical methods for determining error. *Lab Med*. 1996;27:601-606; 5) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition*. CLSI document C24-A3 (ISBN 1-56238-613-1). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006; 6) NCCLS. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline—Second Edition*. NCCLS document EP10-A2 (ISBN 1-56238-482-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002; 7) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3707 [42CFR493.1253].

**GEN.42025****Phase II****N/A YES NO****Has the laboratory verified or established and documented the analytic sensitivity (lower detection limit) of each assay, as applicable?**

*NOTE: For FDA-cleared/approved tests, documentation may consist of data from manufacturers or the published literature.*

**COMMENTARY:**

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7164 [42CFR493.1213]; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):62607-62608 [42CFR493.1253]; 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3707 [42CFR493.1253].

GEN.42030

Phase II

N/A YES NO

**Has the laboratory verified or established and documented analytic interferences for each test?**

*NOTE: Interfering substances may pose a significant problem to the clinical laboratory and healthcare providers who may be misled by laboratory results that do not reflect patient clinical status. The laboratory must be aware of common interferences by performing studies or having available studies performed elsewhere (such as by the instrument-reagent manufacturer).*

COMMENTARY:

N/A

REFERENCES: 1) Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. CLSI document EP7-A2 (ISBN 1-56238-584-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7162 [42CFR493.1253(b)(2)(iv)]; 3) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1994(Dec 6):62607-62608 [42CFR493.1449]; 4) Ho C-H. The hemostatic effect of packed red cell transfusion in patients with anemia. *Transfusion*. 1998;38:1011-1014; 5) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3707 [42CFR493.1253].

GEN.42085

Phase II

N/A YES NO

**Is the reportable range verified/established for each analytic procedure before implementation?**

*NOTE: The reportable range includes all results that may be reliably reported, and embraces two types of ranges:*

1. *The ANALYTICAL MEASUREMENT RANGE (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process*

2. *The CLINICALLY REPORTABLE RANGE (CRR) is the range of analyte values that a method can measure, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct analytical measurement range*

*Expanded definitions and details of the AMR and CRR are provided in some of the section-specific checklists (e.g., Chemistry and Toxicology). Verification of reportable ranges may not apply to certain assays (for example, in immunology and coagulation).*

*The limits of the reportable range are based on meeting accuracy and precision requirements such as the minimal limit of quantification or sensitivity, when applicable. In some cases, clinically relevant limits may be narrower than the potential analytical range, and the clinically relevant limit would be used as the limit of the reportable range.*

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7164 [42CFR493.1213].

**GEN.42140**

**Phase I**

**N/A YES NO**

**Are the laboratory's current test methods, including performance specifications, available to clients upon request?**

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7162 [42CFR493.1109(g)]; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register*. 2003(Jan 24):5230 [42CFR493.12939(e)]; 3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3713 [42CFR493.1290(e)].

**GEN.42160**

**Phase II**

**N/A YES NO**

**If the laboratory changes its analytic methodology so that test results or their interpretations may be SIGNIFICANTLY different, is the change explained to clients?**

*NOTE: This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters, or part of the test report itself.*

## COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7163 [42CFR493.1291(e)]; 2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):3713 [42CFR493.1290(e)].

## REFERENCE INTERVALS

GEN.42162

Phase II

N/A YES NO

**Has the laboratory established or verified its reference intervals (normal values)?**

*NOTE: Reference intervals are important to allow a clinician to assess patient results against an appropriate population. The reference range must be established or verified for each analyte and specimen source (e.g., blood, urine, cerebrospinal fluid), when appropriate. For many analytes (e.g., therapeutic drugs and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.*

## COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7164 [42CFR493.1213]; 2) Van der Meulen EA, *et al.* Use of small-sample-based reference limits on a group basis. *Clin Chem*. 1994;40:1698-170; 3) NCCLS. How to define and determine reference intervals in the clinical laboratory; approved guideline C28-A2. Wayne, PA: NCCLS, 2000.

GEN.42163

Phase II

N/A YES NO

**Does the laboratory evaluate the appropriateness of its reference intervals, and take corrective action if necessary?**

*NOTE: Criteria for evaluation of reference intervals include:*

1. *Introduction of a new analyte to the test repertoire*
2. *Change of analytic methodology*
3. *Change in patient population*

*If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken.*

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7164 [42CFR493.1213]; 2) Van der Meulen EA, *et al*. Use of small-sample-based reference limits on a group basis. *Clin Chem*. 1994;40:1698-170; 3) NCCLS. How to define and determine reference intervals in the clinical laboratory; approved guideline C28-A2. Wayne, PA: NCCLS, 2000.

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## LABORATORY COMPUTER SERVICES

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*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 questions 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 questions N/A. However, the laboratory is responsible for ensuring that the provider of host functions meets CAP requirements (see GEN.42165, below).*

*The questions in this section do NOT apply to the following:*

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

**GEN.42165          Phase II**

**N/A   YES   NO**

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

*NOTE: This question does not apply if all components of the LIS are under the laboratory's CAP/CLIA-88 registration number. This requirement may be addressed by a copy of the CAP accreditation certificate from other sites, or evidence that the computer facility has been provided a copy of this Checklist, and has satisfactorily addressed the contents of the Computer Facility section, and all other pertinent items, with documentation provided to the laboratory director and the CAP inspector.*

COMMENTARY:

N/A

**GEN.42457          Phase II**

**N/A   YES   NO**

**In the judgment of the laboratory director, is the functionality and reliability of the computer system (hardware and software) adequate to meet the needs of patient care?**

*NOTE: Patient and laboratory data should be available online for a reasonable period of time, depending on the needs of the institution. The laboratory director is responsible for determining if the computer system reliability (hardware, software, and/or storage capacity) meets the patient care needs of the organization.*

COMMENTARY:

N/A

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COMPUTER FACILITY

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*This section applies to laboratories where the computer facilities are housed. If the computer facilities are located at another site, mark these 4 questions N/A and continue with the LIS/Computer Procedure Manual section.*



**GEN.42750**                  **Phase I**    **N/A   YES   NO**

**Is the computer facility and equipment 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.*

COMMENTARY:

N/A

**\*\*REVISED\*\***                  **09/27/2007**

**GEN.42800**                  **Phase II**    **N/A   YES   NO**

**Is fire-fighting equipment (extinguishers) appropriate for electrical components available?**

COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association Standard 75: Protection of Information Technology Equipment, 2003. Chapter 8. <http://www.nfpa.org>.

**GEN.42850**                  **Phase I**    **N/A   YES   NO**

**Are all wires and computer cables properly located and/or protected from traffic?**

COMMENTARY:

N/A

**GEN.42900**                  **Phase II**    **N/A   YES   NO**

**Is the computer system 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.*



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.

COMMENTARY:

N/A

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HARDWARE AND SOFTWARE

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GEN.43011      Phase II

N/A   YES   NO

**Is there documentation of all hardware modifications?**

COMMENTARY:

N/A

GEN.43022      Phase II

N/A   YES   NO

**Is there 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.

COMMENTARY:

N/A

GEN.43033      Phase II

N/A   YES   NO

**Are customized programs appropriately documented?**







**GEN.43150****Phase II****N/A YES NO**

**Are there 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.*

COMMENTARY:

N/A

**GEN.43200****Phase I****N/A YES NO**

**Are computer access codes (security codes, user codes) in place to limit individuals' access to those functions they are authorized to use, and is the security of access codes 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.*

COMMENTARY:

N/A

**GEN.43262****Phase I****N/A YES NO**

**Are policies and procedures in place to prevent unauthorized 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.*

COMMENTARY:

N/A

GEN.43325

Phase II

N/A YES NO

**If the facility uses a public network, such as the Internet as a data exchange medium, are there 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. A documented protocol must be in place.*

COMMENTARY:

N/A

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PATIENT DATA  
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**\*\*REVISED\*\***      09/27/2007

GEN.43450

Phase II

N/A YES NO

**Is there documentation that calculated values that generate a patient report are reviewed every two years, or when a system change is made that may affect the calculations?**

*NOTE: This checklist requirement applies to values calculated by the laboratory information system or middleware.*

*Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked and documented to ensure accuracy. Only calculations based on user-modifiable formulas or parameters must be checked. This includes calculations performed by an LIS or middleware system, but would typically not include those performed by an analyzer. Examples of calculations that must be checked include estimated GFR and anion gap. 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.*

COMMENTARY:



N/A

**GEN.43600 Phase I**

**N/A YES NO**

**Are system data tables set up to detect absurd values before reporting?**

*NOTE: Examples of best practices for this step is to check the result against a defined reportable range and critical results for the test, and ensure that the appropriate number of decimal places are present. An audit trail of this process should exist.*

COMMENTARY:

N/A

**GEN.43750 Phase II**

**N/A YES NO**

**Does the system provide for comments on specimen quality that might compromise the accuracy of analytic results (e.g., hemolyzed, lipemic)?**

COMMENTARY:

N/A

**GEN.43800 Phase II**

**N/A YES NO**

**Is there 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.*

COMMENTARY:

N/A

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

**GEN.43812**      **Phase I**      **N/A YES NO**

**Does the laboratory have 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 question 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.*

COMMENTARY:

N/A

**GEN.43825**      **Phase II**      **N/A YES NO**

**Are manual and automated result entries verified before final acceptance and reporting by the computer?**

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

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

COMMENTARY:

N/A

**GEN.43837**      **Phase II**      **N/A YES NO**

**Are there documented procedures to ensure reporting of patient results in a prompt and useful fashion during partial or complete downtime and recovery of the system?**

## COMMENTARY:

N/A

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

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AUTOVERIFICATION

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*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.*

GEN.43850

Phase II

N/A YES NO

**Is there a policy signed by the laboratory director approving the use of autoverification procedures?**

## COMMENTARY:

N/A

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; 3) Nicoli M, *et al.* The use of the Sysmex Co. data processing software program (PC-DPS) for the automatic validation of haematological data. *Clin Chem.* 2000;46:A133; 4) NCCLS. *Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard.* NCCLS document AUTO3-A (ISBN 1-56238-428-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000; 5) Duco DJ. Autoverification in a laboratory information system. *Lab Med.* 2002;33:21-25.

GEN.43875

Phase II

N/A YES NO

**Is there 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?**



**GEN.43887            Phase II                                    N/A    YES    NO**

**Does the audit trail in the computer system identify all test results that were autoverified, and the date/time of autoverification?**

COMMENTARY:

N/A

**GEN.43890            Phase I    N/A    YES    NO**

**Does the autoverification process include all delta checks that the laboratory performs prior to manual release of test results?**

*NOTE: This question 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.*

COMMENTARY:

N/A

**GEN.43893            Phase I    N/A    YES    NO**

**Does the laboratory have a procedure for rapid suspension of autoverification?**

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

COMMENTARY:

N/A

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DATA RETRIEVAL AND PRESERVATION  
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**GEN.43900           Phase II   N/A   YES   NO**

**Can a complete copy of archived patient test results be reprinted, 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.*

COMMENTARY:

N/A

**GEN.43920           Phase I   N/A   YES   NO**

**When multiple identical analyzers are used, are they 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.*

COMMENTARY:

N/A

**GEN.43933           Phase I   N/A   YES   NO**

**Does the laboratory have a process to monitor computer system performance, to ensure that the data storage capacity and performance of the system are sufficient to meet the patient needs of the organization?**

*NOTE: Best practice is to set and monitor thresholds for acceptable storage capacity, average response time and system resource utilization. Laboratory data should be available on-line for a reasonable period of time, which should be determined by the needs of the organization.*

COMMENTARY:

N/A

**GEN.43946           Phase II   N/A   YES   NO**

**Are there 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 do 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 question is often addressed by the organization’s disaster plan.*

COMMENTARY:

N/A

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

**GEN.43972**

**Phase II**

**N/A YES NO**

**Is emergency service for both computer hardware and software available at all necessary times?**

COMMENTARY:

N/A

**GEN.44000**

**Phase II**

**N/A YES NO**

**Are storage data media (e.g., tape reels, disk cartridges) properly labeled, stored and protected from damage and unauthorized use?**

COMMENTARY:

N/A

**\*\*REVISED\*\*            09/27/2007**

**GEN.44100**

**Phase II**

**N/A YES NO**

**Are computer error messages that alert computer users of imminent problems monitored and have such errors been appropriately addressed?**

*NOTE: Computer error messages come in many forms, and usually signify an event that requires immediate attention to rectify a situation. Examples of error messages include system errors, low disk*

*space warnings, database validation errors, exceeding environmental limits, etc. There should be a person responsible for acknowledging the message, a defined system of notification, and response to the situation.*

COMMENTARY:

N/A

**GEN.44150**

**Phase II**

**N/A YES NO**

**Is there documentation of responses to any error messages during the system backup?**

COMMENTARY:

N/A

**GEN.44200**

**Phase II**

**N/A YES NO**

**Is there a documented record of unscheduled downtime, system degradation (response time), or other computer problems that includes reasons for failure and corrective actions taken?**

COMMENTARY:

N/A

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

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INTERFACES

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**GEN.45500**

**Phase I**

**N/A YES NO**

**If the system uses an interface to populate data into another computer system, is a documented encoding and transmission scheme such as HL-7 utilized?**

*NOTE: Interface engines allow data from one computerized database to be translated and automatically entered into another divergent system. A documented encoding and transmission scheme should be utilized to accomplish this task. The most common language used at this time is HL-7.*



COMMENTARY:

N/A

**GEN.46000          Phase I**

**N/A   YES   NO**

**As applicable, are reference ranges and units of measure for every test 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.*

COMMENTARY:

N/A

**GEN.46500          Phase I**

**N/A   YES   NO**

**Are acceptable transmission limits established for data throughput by the interface engine, and is this parameter periodically monitored and recorded?**

*NOTE: One potential bottleneck related to the reporting of results is a backlog of requests to be processed by an interface engine. The laboratory should establish a time tolerance limit for results reporting to the output device. Also, the laboratory should periodically monitor the performance of its reporting systems.*

COMMENTARY:

N/A

**GEN.47000          Phase II**

**N/A   YES   NO**

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

COMMENTARY:

N/A

**GEN.48500****Phase II****N/A YES NO**

**Is there a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (both paper and electronic)?**

*NOTE: Verification must be performed prior to implementation of an interface (i.e., pre go-live), and periodically 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, must be evaluated. When multiple copies of tables are maintained within more than one computer system, they must be periodically compared to ensure consistency among all copies in use.*

*This checklist question applies only to interfaces through which laboratory information systems directly send or receive data. For example, if the laboratory information system is interfaced with the hospital information system, the laboratory must verify the accuracy of patient results transmitted across the interface between the two systems. However, the checklist question would not apply to data transmitted from the hospital information system to a physician office information system.*

COMMENTARY:

N/A

REFERENCE: Cowan DF, *et al.* Validation of the laboratory information system. *Arch Pathol Lab Med.* 1998;122:239-244.

**GEN.48750****Phase II****N/A YES NO**

**Are there 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.*

COMMENTARY:

N/A

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

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NETWORKS  
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**GEN.49000**      **Phase I**      **N/A YES NO**

**Is there periodic monitoring of network performance and availability to all sites?**

*NOTE: Networks are the medium of data transport. Periodic review of collision rates, throughput, and downtimes should be conducted to assist in network maintenance and design.*

COMMENTARY:

N/A

**GEN.49500**      **Phase I**      **N/A YES NO**

**Is the network equipment accessible, well-maintained, and adequately labeled, showing which devices are using a specific port?**

*NOTE: Cables and ports should be monitored so that a device can be found quickly in case of network failure.*

COMMENTARY:

N/A  
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TELEPATHOLOGY  
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*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*



**\*\*NEW\*\*** 09/27/2007

**GEN.51171 Phase I N/A YES NO**

**Do 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.*

COMMENTARY:

N/A

**\*\*NEW\*\*** 09/27/2007

**GEN.51728 Phase I N/A YES NO**

**Does the lab have a procedure addressing training requirements for all users of the telepathology system?**

COMMENTARY:

N/A

**\*\*NEW\*\*** 09/27/2007

**GEN.52285 Phase I N/A YES NO**

**Is telepathology included in the laboratory's quality management program?**

*NOTE: For example, the laboratory might monitor the frequency of deferrals of frozen section diagnoses, including comparison to frozen sections diagnosed by traditional microscopy.*

COMMENTARY:

N/A

**\*\*NEW\*\***

**09/27/2007**

**GEN.52842**

**Phase II**

**N/A YES NO**

**Are there 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.*

**COMMENTARY:**

N/A

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**PERSONNEL**

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*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).*

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**TECHNICAL SUPERVISORS**  
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*This is a position title defined under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) for laboratories performing high complexity tests. 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-88. A laboratory may have multiple technical supervisors. The CAP reserves the right to set requirements that are more stringent than those of CLIA-88. If the laboratory performs only waived and/or moderate complexity tests, or is not subject to CLIA-88, this subsection is not applicable.*

**\*\*REVISED\*\***      **04/06/2006**

**GEN.53400**

**Phase II**

**N/A YES NO**

**Do technical supervisors meet the qualifications defined by CAP and CLIA-88?**

*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-88 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, radiobioassay, immunohematology.*

*CLIA-88 imposes additional requirements for the technical supervisors of the histocompatibility and clinical cytogenetics services. These are found in the Histocompatibility and Cytogenetics Checklists, respectively.*

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7177 [42CFR493.1449].

**GEN.53500**

**Phase II**

**N/A YES NO**

**Do technical supervisors fulfill the responsibilities defined by CLIA-88?**

*NOTE: The technical supervisors of high complexity testing, as designated by the laboratory director, are responsible for the technical and scientific oversight of the laboratory. Specific details are found in Fed Register. 1992(Feb 28):7180-7181 [42CFR493.1451].*

COMMENTARY:

N/A

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

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GENERAL SUPERVISORS

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*This is a position title defined under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) for laboratories performing high complexity tests. 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-88. A laboratory may have multiple general supervisors. The CAP reserves the right to set requirements that are more stringent than those of CLIA-88. If the laboratory performs only waived and/or moderate complexity tests, or is not subject to CLIA-88, this section is not applicable.*

*If the laboratory is not subject to CLIA-88, mark all questions in this section N/A.*

GEN.53600

Phase II

N/A YES NO

**Do general supervisors meet the qualifications defined by CLIA-88?**

*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-88 requirements for the general supervisors of cytopathology and blood gas analysis are found in the Cytopathology checklist and Chemistry and Toxicology checklist.*

COMMENTARY:

N/A



REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7181 [42CFR493.1461].

**GEN.53700****Phase II****N/A YES NO**

**Do general supervisors fulfill the responsibilities defined by CLIA-88?**

*NOTE: 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. Specific details are found in Fed Register. 1992(Feb 28):7182 [42CFR493.1463]*

COMMENTARY:

N/A

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

-----  
ALL PERSONNEL  
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**GEN.54000****Phase II****N/A YES NO**

**Is there 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?**

COMMENTARY:

N/A

**GEN.54100****Phase II****N/A YES NO**

**Are there documented personnel policies?**

COMMENTARY:

N/A

**GEN.54200 Phase I N/A YES NO**

**Is there a functional continuing clinical laboratory education program adequate to meet the needs of all personnel?**

COMMENTARY:

N/A

REFERENCES: 1) Von Needa P. Keep everyone keen on continuing education. *Med Lab Observ.* 1979(May):117-126; 2) Berry CD. The JCAH approach to continuing education in the clinical laboratory. *Lab Med.* 1981;12:10-11; 3) Umiker W. The role of the pathologist in continuing education programs for laboratory personnel. *Lab Med.* 1981;12:18-21; 4) Yapit MK. Resources and strategies for a successful CE program. *Med Lab Observ.* 1989(Apr):47-566; 5) Tiehen A. Competency assessment in the transfusion service. *Med Lab Observ.* 1993;25(10):35-42; 6) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827; 7) Nguyen AND, *et al.* A web-based teaching program for laboratory diagnosis of coagulation disorders. *Arch Pathol Lab Med.* 2000;124:588-593.

**GEN.54300 Phase II N/A YES NO**

**Are personnel files maintained on all current employees?**

*NOTE: The ideal location of personnel files is in the laboratory, but they may be kept in the personnel office or health clinic if the laboratory has ready access to them.*

COMMENTARY:

N/A

**\*\*REVISED\*\* 10/31/2006**

**GEN.54400 Phase II N/A YES NO**

**Do technical personnel records include all of the following mandatory items?**

- 1. Summary of training and experience**
- 2. Formal certification or license, if required by state**
- 3. Description of current duties (may be generic to a position)**
- 4. Records of continuing education**
- 5. 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**

- 6. **Work-related incident and/or accident records**
- 7. **Dates of employment**

*NOTE: The inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.*

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Training and Competence Assessment; Approved Guideline—Second Edition*. NCCLS document GP21-A2 (ISBN 1-56238-531-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 2) Harmening DM, *et al*. Defining roles of medical technologists and medical laboratory technicians. *Lab Med*. 1995;26:175-178; 3) Ward-Cook K, *et al*. Medical technologist core job tasks still reign. *Lab Med*. 2000;31:375-379.

**GEN.54750          Phase II          N/A   YES   NO**

**For laboratories subject to US federal regulations, do all testing personnel meet CLIA-88 requirements?**

*NOTE: There must be evidence in personnel records that all testing personnel have been evaluated against CLIA-88 requirements, and that all individuals qualify.*

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7175 [42CFR493.1423], 7183 [42CFR493.1489]; 2) NCCLS. *Training and Competence Assessment; Approved Guideline—Second Edition*. NCCLS document GP21-A2 (ISBN 1-56238-531-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

**GEN.55200          Phase II          N/A   YES   NO**

**Are there annual reviews of the performance of existing employees and an initial review of new employees within the first six months?**

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.1413(b)(9)]; 2) NCCLS. *Training and Competence Assessment; Approved Guideline—Second Edition*. NCCLS document GP21-A2 (ISBN 1-56238-531-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 3) Schiffgens J, Bush VA. Four-part approach to competency assessment. *Lab Med*. 2001;32:431-435.

**GEN.55400**                      **Phase I**    **N/A**   **YES**   **NO**

**Are technical personnel 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.*

**COMMENTARY:**

N/A

**\*\*REVISED\*\***                      **09/27/2007**

**GEN.55500**                      **Phase II**    **N/A**   **YES**   **NO**

**Has the competency of each person to perform his/her assigned duties been assessed?**

*NOTE: The manual that describes training activities and evaluations must be specific for each job description. Those activities requiring judgment or interpretive skills must be included. The records must make it possible for the inspector to determine what skills were assessed and how those skills were measured. The competency of each person to perform the duties assigned must be assessed following training, and at least annually thereafter. During the first year of an individual's duties, competency must be assessed at least every six months. 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*

*It may not be necessary to assess all of the above elements for each individual on an annual basis. The Program Director should identify and incorporate the elements most pertinent to the testing being performed.*

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1065-66 [42CFR493.1451(b)], 1053-54 [42CFR493.1413], 1992 (Feb 28) 7184 [42CFR493.1713] ; 2) Tiehen A. Competency assessment in the transfusion service. *Med Lab Observ*. 1993;25(10):35-42; 3) Harmening DM, *et al*. Defining the roles of medical technologists and medical laboratory technicians. *Lab Med*. 1995;26:175-178; 4) NCCLS. *Training and Competence Assessment; Approved Guideline—Second Edition*. NCCLS document GP21-A2 (ISBN 1-56238-531-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 5) Blackledge L. Professional perspectives. Why I hire certified technologists. *Lab Med*. 1999;30:503-504; 6) Boone DJ. Assessing laboratory employee competence. *Arch Pathol Lab Med*. 2000;124:190-191; 7) Howanitz PJ, *et al*. Employee competence and performance-based assessment. A College of American Pathologists Q-Probes study of laboratory personnel in 522 institutions. *Arch Pathol Lab Med*. 2000;124:195-202; 8) Church DL, *et al*. Effects of restructuring on the performance of microbiology laboratories in Alberta. *Arch Pathol Lab Med*. 2000;124:357-361; 9) Ward-Cook K, *et al*. Medical technologist core job tasks still reign. *Lab Med*. 2000;31:375-379; 10) Haun DE, *et al*. Assessing the competence of specimen-processing personnel. *Lab Med*. 2000;31:633-637; 11) Schiffgens J, Bush VA. Four-part approach to competency assessment. *Lab Med*. 2001;32:431-435.

GEN.57000

Phase I

N/A YES NO

**If an employee fails to demonstrate satisfactory performance on the competency assessment, does the laboratory have 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.*

COMMENTARY:

N/A

**GEN.58500**

**Phase I**

**N/A YES NO**

**Is there documentation of retraining and reassessment for employees who initially fail to demonstrate satisfactory performance on competency assessment?**

COMMENTARY:

N/A

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**PHYSICAL FACILITIES**

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SPACE

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*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**

**Phase II**

**N/A YES NO**

**Does the general laboratory have adequate, conveniently located space so the quality of work, safety of personnel, and patient care services are not compromised?**

*NOTE: If the answer to this question is "NO," the inspector must attach detailed notes and descriptions to the Inspector Summation Report.*

COMMENTARY:

N/A

REFERENCES: 1) Koenig AS. Medical laboratory planning and design. Northfield, IL: College of American Pathologists, 1992; 2) Guidelines for construction and equipment for hospital and medical facilities. Washington, DC: American Institute of Architects Press, 1993; 3) Cooper EC. Laboratory design handbook. London: CRC Press, 1994; 4) Mortland KK, Reddick JH. Laboratory design for today's technologies and marketplace. *Lab Med.* 1997;28:332-336; 5) NCCLS. Laboratory design;



**GEN.61400      Phase I      N/A   YES   NO**

**Are passageways unobstructed?**

COMMENTARY:

N/A

**GEN.61500      Phase I      N/A   YES   NO**

**Are floors, walls and ceilings clean and well-maintained?**

COMMENTARY:

N/A

**GEN.61600      Phase I      N/A   YES   NO**

**Are bench tops, cupboards, drawers and sinks clean and well-maintained?**

COMMENTARY:

N/A

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

**GEN.61700      Phase I      N/A   YES   NO**

**Is general intralaboratory communication effective and efficient?**

COMMENTARY:

N/A



**GEN.61750**

**Phase I**

**N/A YES NO**

**Has the laboratory implemented 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.*

COMMENTARY:

N/A

**GEN.61800**

**Phase I**

**N/A YES NO**

**Are telephones and computer terminals conveniently located?**

COMMENTARY:

N/A

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**INVENTORY AND STORAGE OF SUPPLIES**  
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**GEN.61900**

**Phase I**

**N/A YES NO**

**Is there an effective supply inventory control system in operation?**

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

COMMENTARY:

N/A

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

GEN.62000      Phase I      N/A   YES   NO

**Is the intralaboratory storage area sufficient?**

COMMENTARY:

N/A

GEN.62100      Phase I      N/A   YES   NO

**Are storage areas well-organized and free of clutter?**

COMMENTARY:

N/A

GEN.62200      Phase II      N/A   YES   NO

**Is the central or main refrigerated storage area monitored for temperature control?**

*NOTE: If the laboratory uses a central refrigerated storage unit, it must be controlled by an upper and lower alarm system, or a recording thermometer, or both. Records of temperature must be maintained. If there is no central refrigerated storage area either within the laboratory or elsewhere, mark this question "N/A."*

COMMENTARY:

N/A

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POWER  
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GEN.66100      Phase I      N/A   YES   NO

**Is emergency power 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.*

COMMENTARY:

N/A

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**LABORATORY SAFETY**

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*Questions 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 questions in any one section of the laboratory represents a deficiency for the entire laboratory. Specific questions related to safety features peculiar to an individual section will be found in the checklist for that section.*

*This safety section is divided into two portions to facilitate the inspection. The first portion (MANUALS AND RECORDS) relates to review of documentation. The laboratory should gather these documents together for review by the inspector. The second portion (PHYSICAL INSPECTION OF THE LABORATORY) requires direct inspection of the various laboratory areas to observe environmental safety compliance and actual employee practices.*

*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.*

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**MANUALS AND RECORDS**

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**GEN.70000      Phase II      N/A   YES   NO**

**Are safety policies and procedures 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.*

COMMENTARY:

N/A

REFERENCES: 1) Montgomery L. Health and safety guidelines for the laboratory. Chicago, IL: American Society of Clinical Pathologists Press, 1995; 2) NCCLS. *Clinical Laboratory Safety*;



*NOTE: For U.S. 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.*

COMMENTARY:

N/A

REFERENCE: *Fed Register*. 1986;50(137):29102-29113; 2) 29CFR1904.8, current edition.

**GEN.70150**

**Phase II**

**N/A YES NO**

**Has an evaluation of these occupational injury/illness reports been incorporated into the laboratory's quality management program to avoid recurrence?**

COMMENTARY:

N/A

**GEN.70200**

**Phase II**

**N/A YES NO**

**Are policies and procedures documented and adequate for fire prevention and control?**

COMMENTARY:

N/A

REFERENCES: 1) Stern A, *et al*. Fire safety in the laboratory: part I. *Lab Med*. 1993;24:275-277; 2) Stern A, *et al*. Fire safety in the laboratory: part II. *Lab Med*. 1993;24:350-352; 3) NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition*. NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 4) Hoeltge GA, *et al*. Accidental fires in clinical laboratories. *Arch Pathol Lab Med*. 1993;117:1200-1204.

**GEN.70250**

**Phase II**

**N/A YES NO**

**Are fire drills conducted periodically?**

*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.*

## COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals, Chapter 6. Quincy, MA: NFPA, 2004; 3) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.70300****Phase II****N/A YES NO****Have personnel been instructed in the use of portable fire extinguishers?**

*NOTE: There must be documentation that laboratory personnel have been trained to use fire extinguishers. 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.*

## COMMENTARY:

N/A

REFERENCES: 1) Stern A, *et al.* Fire safety in the laboratory: part I. *Lab Med.* 1993;24:275-277; 2) Stern A, *et al.* Fire safety in the laboratory: part II. *Lab Med.* 1993;24:350-352; 3) NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition.* NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 4) National Fire Protection Association. NFPA 10: Standard for Portable Fire Extinguishers. Quincy, MA: NFPA, 2007; 5) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204.

**GEN.70350****Phase II****N/A YES NO****Are policies and procedures documented and adequate for the safe handling of electrical equipment?**

*NOTE: Policies must specify that portable patient care electrical equipment be inspected before initial use, after repair or modification, and when a problem is suspected.*

## COMMENTARY:

N/A

REFERENCE: NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition*. NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

GEN.70450

Phase II

N/A YES NO

**Does the laboratory have a Chemical Hygiene Plan (CHP) that defines the safety procedures for all hazardous chemicals used in the laboratory?**

*NOTE: The laboratory director or designee must ensure that the laboratory has a documented chemical hygiene plan (CHP) that defines the safety procedures 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 qualified chemical hygiene officer*
3. *Policies for all operations that involve hazardous 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*

COMMENTARY:

N/A

REFERENCES: 1) Occupational Safety and Health Administration. Toxic and hazardous substances hazard communication: standard. 1985: [29CFR1910.1200]; 2) Occupational Safety and Health Administration. Occupational exposures to hazardous chemicals in laboratories: standard. 1990: [29CFR1910.1450]; 3) Karcher RE. Is your chemical hygiene plan OSHA-proof? *Med Lab Observ.* 1993(Jul):29-36; 4) Occupational Safety and Health Administration. Occupational exposure to methylene chloride: standard. 1997: [29CFR1910;1915;1926]; 5) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med.* 1999;30:710.

**GEN.70500 Phase II N/A YES NO**

**Is there annual review and evaluation of effectiveness of the laboratory's Chemical Hygiene Plan?**

COMMENTARY:

N/A

**GEN.70512 Phase I N/A YES NO**

**Does the laboratory have a written plan to reduce or eliminate mercury?**

*NOTE: Based on the mercury reduction goal presented by the Environmental Protection Agency (EPA) and the American Hospital Association to eliminate mercury from hospitals by 2005, the laboratory needs a plan to reduce or eliminate mercury. In addition to the mercury in thermometers and sphygmomanometers, small quantities may be found in some fixatives (e.g., B-5), and mercury may be used in parasitology concentration procedures. Substitutes for mercury in these applications are encouraged.*

COMMENTARY:

N/A

REFERENCE: Brossard LA, *et al.* The Toxicology of Mercury. *Lab Med* 2000; 33 (Aug).

**GEN.70525 Phase I N/A YES NO**

**Are adequate policies, procedures, and practices 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*

COMMENTARY:

N/A

REFERENCE: OSHA Technical Link "Nitrogen" dated 4/27/1999 > [<http://www.osha-slc.gov/SLTC/healthguidelines/nitrogen/index.html>].



**GEN.70550****Phase II****N/A YES NO**

**Is there documentation that each of the chemicals in the laboratory has been evaluated for carcinogenic potential, reproductive toxicity, and acute toxicity; and does the policies and procedure manual define specific handling requirements for these chemicals?**

*NOTE: OSHA defines the substances of special interests (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. There must be specific handling requirements defined for each chemical in use that is potentially carcinogenic.*

*Authoritative sources include (but are not limited to) OSHA (Code of Federal Regulations, Title 29, Part 1910.1001-1047, 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.*

COMMENTARY:

N/A

REFERENCES: 1) Occupational Safety and Health Administration. Toxic and hazardous substances hazard communication: standard. 1985: [29CFR1910.1200]; 2) Occupational Safety and Health Administration. Occupational exposures to hazardous chemicals in laboratories: standard. 1990: [29CFR1910.1450]; 3) Karcher RE. Is your chemical hygiene plan OSHA-proof? *Med Lab Observ.* 1993(Jul):29-36; 4) Occupational Safety and Health Administration. Occupational exposure to methylene chloride: standard. 1997: [29CFR1910;1915;1926].

**GEN.70600****Phase II****N/A YES NO**

**Are policies and procedures documented and adequate for hazardous waste disposal?**

*NOTE: The laboratory is responsible for all real or potential hazards of wastes at all stages of disposal including transportation and final disposition.*

COMMENTARY:

N/A

REFERENCES: 1) Ornelas D, *et al.* The laboratory's role in reducing hazardous waste. *Lab Med.* 1998;29:287-290; 2) Ornelas D, *et al.* The role of recycling and chemical substitution in pollution prevention programs. *Lab Med.* 1998;29:356-359; 3) Reinhart DR, McCreanor PT. Medical waste management: where does the solid waste go? *Lab Med.* 2000;31:141-145; 4) NCCLS. Clinical laboratory waste management; approved guideline-second edition; approved guideline GP5-A2. Wayne, PA: NCCLS, 2002.

GEN.70650

Phase II

N/A YES NO

**Is the method for the disposal of all solid and liquid wastes in compliance with local, state and federal regulations?**

*NOTE: Whether or not laboratory management is responsible for waste disposal, the laboratory should have documentation that the facility is in compliance with all applicable regulations. Prevailing local, state and federal (EPA) regulations should be reviewed by the laboratory director, safety officer or hospital engineer to be sure that the laboratory is in compliance with regulations.*

COMMENTARY:

N/A

GEN.70700

Phase I

N/A YES NO

**Is there a program to reduce the volume of hazardous waste that is generated by the laboratory?**

*NOTE: This includes any activity that reduces the volume of hazardous waste generated or the degree of hazard that is posed by that waste to the environment. In general, there are 5 methods for a laboratory to consider:*

1. *Acquisition constraints (e.g., purchase reagents in small quantities; minimize specimen volumes taken from patients)*
2. *Process changes (e.g., substitute less hazardous reagents for more hazardous ones; adopt techniques that require smaller reagent volumes; avoid excessive specimen retention times)*
3. *Recovery (e.g., silver recovery from darkroom fluids; heat recovery from the combustion of waste solvent)*
4. *Recycling (e.g., distillation and reuse of xylene or formalin)*
5. *Redistribution (e.g., relocating surplus or unwanted chemicals to laboratories that can use them)*



**GEN.70816                  Phase II    N/A   YES   NO**

**Is there a documented ergonomics program to prevent musculoskeletal disorders (MSDs) in the workplace through prevention and engineering controls?**

*NOTE: A comprehensive ergonomics program to prevent the occurrence of work-related MSDs 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.*

COMMENTARY:

N/A

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

**\*\*NEW\*\*                          04/06/2006**

**GEN.70824                  Phase I    N/A   YES   NO**

**Does the laboratory have 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).*

COMMENTARY:

N/A

REFERENCE: U. S. Department of Labor, Occupational Safety & Health Administration:  
[http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_id=9735&p\\_table=STANDARDS](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9735&p_table=STANDARDS).

**GEN.70832                  Phase II    N/A   YES   NO**

**Are policies documented to prevent or reduce ultraviolet light exposure from instrument sources?**



Cibull ML. Handling sentinel lymph node biopsy specimens. A work in progress. *Arch Pathol Lab Med.* 1999;123:620-62; 4) Pfeifer JD. Sentinel lymph node biopsy. *Am J Clin Pathol.* 1999;112:599-60; 5) Barnes CA. False-negative frozen section results. *Am J Clin Pathol.* 2000;113:90; 6) Fitzgibbons PL, *et al.* Recommendations for handling radioactive specimens obtained by sentinel lymphadenectomy. *Am J Surg Pathol.* 2000;24:1549-1551.

GEN.70950

Phase II

N/A YES NO

**Does the laboratory have a documented policy for infection control that complies with the OSHA Standard on occupational exposure to bloodborne pathogens and to the institution's exposure control plan?**

*NOTE: Universal or standard precautions must be used when handling all blood and body fluid specimens. The term "universal precautions" refers to a concept of bloodborne disease control requiring all human blood and other potentially infectious materials to be treated as if infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived "low risk" status of a patient or patient population. Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These latter terms define all body fluids and substances as infectious. All health care workers must routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with blood or other body fluids is anticipated. Policies must comply with the OSHA Standard on Bloodborne Pathogens.*

COMMENTARY:

N/A

REFERENCES: 1) Ipolito G. The risk of occupational human immunodeficiency virus infection in health care workers. *Arch Intern Med.* 1993;153:1451-1458; 2) Howanitz PJ, Schifman RB. Safety practices and infectious risks for laboratory phlebotomists. *Am J Clin Pathol.* 1994;102:553; 3) The Hospital Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention, Public Health Service. Guidelines for isolation precautions in hospitals. Part II. Recommendations for isolation precautions in hospitals. February 1996; 4) McGovern PM, *et al.* Laboratory professionals' compliance with universal precautions. *Lab Med.* 1997;28:725-730; 5) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 6) Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition.* CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**\*\*REVISED\*\***      **04/06/2006**

**GEN.71000**      **Phase II**      **N/A YES NO**

**Are there documented procedures detailing procurement, transportation, and handling of patient specimens (blood, body fluids, tissue) to ensure that all specimens are submitted in an appropriately labeled and well-constructed container with a secure lid to prevent leakage during transport?**

*NOTE: Specimens sent through pneumatic tube systems should be sealed in fluid-tight bags. If pneumatic tube systems are used for transporting specimens, the laboratory must have procedures to respond to a spill within the tube, including appropriate decontamination measures.*

COMMENTARY:

N/A

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

**GEN.71008**      **Phase II**      **N/A YES NO**

**Are there documented procedures for handling spills of blood and other body fluids?**

COMMENTARY:

N/A

**GEN.71016**      **Phase II**      **N/A YES NO**

**Has the laboratory evaluated the effectiveness of its engineering and work practice controls in significantly reducing or eliminating exposure to bloodborne pathogens during phlebotomy and laboratory testing?**

*NOTE: "Engineering controls" means controls that isolate or remove the bloodborne pathogens hazard from the workplace (e.g., needleless devices, shielded needle devices, blunt needles, plastic capillary tubes, etc.). "Work practice" controls are those human activities that reduce exposure risk (e.g., no-hands procedures in discarding contaminated sharps, not directly transferring a sharp from one person to another, etc.).*

*The application of engineering and work practice controls can significantly reduce or eliminate exposure to bloodborne pathogens during phlebotomy and laboratory testing. As stated by the U.S. Occupational Safety and Health Administration, preventing exposures requires a comprehensive program, including engineering and work practice controls.*

COMMENTARY:

N/A

REFERENCES: 1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030] ; 2) Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens. 2001(Jan 18): 66CFR5318-5325; 3) NCCLS. Implementing a needlestick and sharps injury prevention program in the clinical laboratory; report X3-R. Wayne, PA: NCCLS, 2002.

**GEN.71032**

**Phase I**

**N/A YES NO**

**Has the laboratory discontinued use of plain glass capillary tubes for specimen collection and specimen handling?**

*NOTE: A 2/22/99 advisory letter from the U.S. Food and Drug Administration, National Institute for Occupational Safety and Health, Centers for Disease Control, and the Occupational Safety and Health Administration concerns the potential risk of injury and/or infection due to accidental breakage of glass capillary tubes. To reduce the risk of injury due to breakage of glass capillary tubes, laboratories should adopt blood collection devices that are less prone to accidental breakage, including:*

1. *Capillary tubes not made of glass*
2. *Glass capillary tubes wrapped in puncture-resistant film*
3. *Products that use a method of sealing that does not require manually pushing one end of the tube into putty to form a plug*
4. *Products that allow the hematocrit to be measured without centrifugation*

COMMENTARY:

N/A

REFERENCES: 1) Aoun H. When a house officer gets AIDS. *New Eng J Med.* 1989;321:693-696; 2) Jagger J, *et al.* Sharp object injuries in the hospital; causes and strategies for prevention. *Am J Infect Control.* 1990;18:227-230; 3) Hudson M, *et al.* Potential hazards with fine bore capillary tubes used by non-pathology staff. *J Hosp Infect.* 1994;28:323-324; 4) Jagger J, Deitchman S. Hazards of glass capillary tubes to health care workers. *JAMA.* 1998;280:31; 5) Jagger J, *et al.* Glass capillary tubes: eliminating an unnecessary risk to health care workers. *Adv Exp Prev.* 1998;3(5):49-55; 6) NCCLS. Implementing a needlestick and sharps injury prevention program in the clinical laboratory; report X3-R. Wayne, PA: NCCLS, 2002.



**GEN.71050      Phase II      N/A   YES   NO**

**Have personnel been instructed in the proper use of personal protective clothing/equipment (e.g., gloves, gowns, masks, eye protectors, etc.)?**

*NOTE: Appropriate personal protective equipment (PPE) are items that do not permit blood or other potentially infectious material to pass through to the skin. Open-toe footwear does not provide adequate protection and should not be worn in the laboratory.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Murray RL. Keep wearing your gloves. *Med Lab Observ.* 1994(Mar):80; 2) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-827; 3) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med.* 1999;30:710; 4) Rego A, Roley L. In-use barrier integrity of gloves: latex and nitrile superior to vinyl. *Am J Infect Control.* 1999;27:405-410; 5) Department of Labor, Occupational Safety and Health Administration, Occupational Safety and Health Standards. Bloodborne pathogens. *Fed Register.* 2002(July 1): [29CFR1910.1030(d)(3)(i)].

**GEN.71100      Phase II      N/A   YES   NO**

**Have all personnel reasonably expected to have direct contact with body fluids received education on precautionary measures, epidemiology, modes of transmission and prevention of human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B virus (HBV) and the application of "universal precautions" or "standard precautions" to their work practices?**

**COMMENTARY:**

N/A

**REFERENCES:** 1) Krienitz DR. Safety education in the laboratory. *Lab Med.* 1996;27:823-287; 2) The Hospital Infection Control Practices Advisory Committee, Centers for Disease Control and Prevention, Public Health Service. Guidelines for isolation precautions in hospitals. Part II. Recommendations for isolation precautions in hospitals. February 1996; 3) Bush VJ, *et al.* Advancements in blood collection devices. *Lab Med.* 1998;29:616-622; 4) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 5) Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition.* CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**GEN.71150 Phase II N/A YES NO**

**Have personnel reasonably expected to have direct contact with body fluids been identified and offered hepatitis B vaccinations free of charge?**

COMMENTARY:

N/A

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

**GEN.71200 Phase II N/A YES NO**

**Is there 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 health-care 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**

COMMENTARY:

N/A

REFERENCES: 1) Alpert LI. Managing needlestick accidents in the lab. Northfield, IL: College of American Pathologists CAP Today 1991(Jun);5(6):49; 2) NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition*. NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 3) Dale JC, *et al*. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc*. 1998;73:611-615; 4) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]4; 5) Tarapchak P. Taking care of 'risky' business. *Advance/Lab*. 1999;8(7):69-73; 6) Shen C, *et al*. Risk of needle stick and sharp object injuries among medical students. *Am J Infect Control*. 1999;27:435-437; 7) Bryce EA, *et al*. Sharps injuries: defining prevention priorities. *Am J Infect Control*. 1999;27:447-455.

**GEN.71220****Phase II****N/A YES NO****Does the laboratory have 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.*

COMMENTARY:

N/A

REFERENCES: 1) Centers for Disease Control and Prevention/National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Washington, DC: US government printing office, May 1993:95; 2) Centers for Disease Control and Prevention. Guidelines for preventing the transmission of tuberculosis in health care facilities. *Fed Register*. 1993(Oct 12);58:52810-52854.

**GEN.71235****Phase I****N/A YES NO****Does the laboratory have 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*

COMMENTARY:

N/A

REFERENCES: 1) Bauer X, *et al*. Health risk in hospitals through airborne allergens for patients pre-sensitized to latex. *Lancet*. 1993;342:1148-1149; 2) Yassin ME, *et al*. Latex allergy in hospital employees. *Ann Allergy*. 1994;72:245-249; 3) Tomazic VJ, *et al*. Cornstarch powder on latex products is an allergen carrier. *J Allergy Clin Immunol*. 1994;93:751-758; 4) Yunginger JW, *et al*. Extractable latex allergens and proteins in disposable medical gloves and other rubber products. *J Allergy Clin*

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

GEN.71250

Phase II

N/A YES NO

**Is there a documented policy that prohibits smoking, eating, drinking, application of cosmetics and lip balm, manipulation of contact lenses, and mouth pipetting in all technical work areas?**

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition.* NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030].

GEN.71300

Phase II

N/A YES NO

**Is there a documented policy prohibiting the recapping, purposeful bending, breaking, removing from disposable syringes, or other manual manipulations of needles?**

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

## COMMENTARY:

N/A

REFERENCES: 1) Jagger J, *et al.* Rates of needlestick injury caused by various devices. *New Engl J Med.* 1988;319:284-288; 2) Whitby M, *et al.* Needlestick injury: impact of a recapping device and an associated education program. *Infect Control Hosp Epidemiol.* 1991;12:220-225; 3) Bush VJ, *et al.* Advancements in blood collection devices. *Lab Med.* 1998;29:616-622; 4) Dale JC, *et al.* Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615; 5) Charney E. Retractable safety syringe activation study. *J Healthcare Safety Compliance Infect Control.* 1998;2(9):413-415; 6) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 7) Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition.* CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

GEN.71350

Phase II

N/A YES NO

**Is there documented periodic review (at least annually) of safe work practices, e.g., by a safety committee?**

*NOTE: This review may be documented by safety committee minutes or by the records of regular safety inspections.*

## COMMENTARY:

N/A

REFERENCE: National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

GEN.71450

Phase II

N/A YES NO

**Is there a function verification program for chemical fume hoods required by the laboratory's Chemical Hygiene Plan?**

## COMMENTARY:

N/A

REFERENCE: Occupational Safety and Health Administration. Toxic and hazardous substances. Occupational exposure to hazardous chemicals in laboratories. US Government Printing Office, 1999(Jul 1): [29CFR1910.1450].

GEN.71500

Phase II

N/A YES NO

**Are all sterilizing devices 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.*

COMMENTARY:

N/A

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PHYSICAL INSPECTION OF THE LABORATORY  
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GEN.71550

Phase II

N/A YES NO

**Is the laboratory properly separated from inpatient areas and/or provided with automatic fire extinguishing (AFE) systems?**

*NOTE: For those facilities with no inpatients, or those separated by 2-hour construction (rated at 1.5 hours) and Class B self-closing doors (SCD), no AFE system is required. An AFE system is required for those laboratories separated from inpatient areas by 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 ft<sup>2</sup>, 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*

## COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 30: Flammable and Combustible Liquids Code. Quincy, MA: NFPA, 2003; 3) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities. Quincy, MA: NFPA, 2005.

**GEN.71600****Phase II****N/A YES NO**

**Does each room larger than 1000 ft<sup>2</sup>, or in which major fire hazards exist, have at least 2 exit access doors remote from each other, one of which opens directly into an exit route?**

## COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals . Quincy, MA: NFPA, 2004; 3) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.71650****Phase II****N/A YES NO**

**Is there an automatic fire detection and alarm system?**

*NOTE: 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.*

## COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.71700****Phase II****N/A YES NO**

**Is the fire alarm audible in all parts of the laboratory, including storage areas, lavatories, and darkrooms?**

*NOTE: Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.*

COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals, Chapter 6. Quincy, MA: NFPA, 2004; 3) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.71750**

**Phase II**

**N/A YES NO**

**Is there 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.*

COMMENTARY:

N/A

REFERENCES: 1) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204; 2) National Fire Protection Association. NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals, Chapter 6. Quincy, MA: NFPA, 2004; 3) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.71800**

**Phase II**

**N/A YES NO**

**Are appropriate portable fire extinguishers 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.*

COMMENTARY:

N/A



REFERENCES: 1) National Fire Protection Association. NFPA 10: Standard for Portable Fire Extinguishers. Quincy, MA: NFPA, 2007; 2) Stern A, *et al.* Fire safety in the laboratory. Part I. *Lab Med.* 1993;24:275-277; 3) Stern A, *et al.* Fire safety in the laboratory. Part II. *Lab Med.* 1993;24:350-352; 4) Hoeltge GA, *et al.* Accidental fires in clinical laboratories. *Arch Pathol Lab Med.* 1993;117:1200-1204.

**GEN.71850**

**Phase II**

**N/A YES NO**

**Is emergency lighting adequate for safe evacuation of the laboratory?**

COMMENTARY:

N/A

**GEN.71950**

**Phase I**

**N/A YES NO**

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

COMMENTARY:

N/A

REFERENCES: 1) National Fire Protection Association. NFPA 99: Health Care Facilities. Quincy, MA: NFPA, 2005; 2) Occupational Safety and Health Administration. Electrical. Use of equipment. US Government Printing Office, 1999(Jul 1): [29CFR1910.334].

**GEN.72000****Phase I****N/A YES NO**

**Are safety cans used instead of glass bottles for volumes of flammable solvents larger than one quart (or larger than one pint for solvents that are highly volatile such as isopentane) if the purity required does not mandate glass storage?**

*NOTE: 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.*

COMMENTARY:

N/A

REFERENCE: National Fire Protection Association. NFPA 30: Flammable and Combustible Liquids Code. Quincy, MA: NFPA, 2003.

**GEN.72050****Phase II****N/A YES NO**

**Are supplies of flammable and combustible liquids reasonable for the laboratory's needs, and are they properly stored?**

*NOTE: 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 ft<sup>2</sup> 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 ft<sup>2</sup>. These amounts may be doubled if there is an automatic fire suppression system (e.g., sprinklers).*

COMMENTARY:

N/A

REFERENCES: 1) National Fire Protection Association. NFPA 30: Flammable and Combustible Liquids Code. Quincy, MA: NFPA, 2003; 2) National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**\*\*NEW\*\***                      **04/06/2006**

**GEN.72075**                      **Phase I**    **N/A YES NO**

**Are supplies of acids and bases stored in separate cabinets near floor level?**

*NOTE: Acids and bases should not be stored under sinks, where contamination by moisture may occur.*

COMMENTARY:

N/A

**GEN.72100**                      **Phase II**    **N/A YES NO**

**Are storage areas and/or rooms where volatile solvents are used 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.*

COMMENTARY:

N/A

REFERENCE: National Fire Protection Association. NFPA 30: Flammable and Combustible Liquids Code. Quincy, MA: NFPA, 2003.

**GEN.72150**                      **Phase II**    **N/A YES NO**

**Are flammable or combustible liquids or gas cylinders positioned well away from open flame or other heat sources, not in corridors and not within exhaust canopies?**

COMMENTARY:

N/A

REFERENCE: National Fire Protection Association. NFPA 99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.72200**      **Phase I**      **N/A YES NO**

**If flammable or combustible solvents are transferred to or from bulk containers, are the primary (source) and secondary (receiving) containers electrically connected and grounded?**

*NOTE: Transfer of flammable liquid from bulk storage containers should be made in storage rooms as described in NFPA 30. If both the source and receiving containers are made of conductive material (e.g., metal), they should be electrically connected (bonded), and the combination grounded, to prevent static electrical discharge.*

COMMENTARY:

N/A

REFERENCES: 1) National Fire Protection Association. NFPA 77: Recommended Practice on Static Electricity. Quincy, MA: NFPA, 2007; 2) National Fire Protection Association. NFPA 30: Flammable and Combustible Liquids Code. Quincy, MA: NFPA, 2003.

**GEN.72250**      **Phase I**      **N/A YES NO**

**Are flammable-gas cylinders, if inside a health care facility, stored in a separate, ventilated room or enclosure, reserved exclusively for that purpose, and which has a fire-resistance classification of at least two hours?**

COMMENTARY:

N/A

REFERENCE: National Fire Protection Association. NFPA99: Standard for Health Care Facilities, Chapter 11. Quincy, MA: NFPA, 2005.

**GEN.72300**      **Phase II**      **N/A YES NO**

**Is there no more than one extra cylinder of compressed, flammable gas (other than those actually connected for use) at any one workstation?**

*NOTE: As an exception, small cylinders (e.g., propane), may aggregate to a 2-day working supply at the workstation.*

COMMENTARY:

N/A



*NOTE: 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.*

*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.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Centers for Disease Control. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. *MMWR*. 1989;38(suppl S-6):1-37; 2) Krienitz DR. Safety education in the laboratory. *Lab Med*. 1996;27:823-827; 3) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 4) Prinz Luebbert P. Q&A. Wearing laboratory coats during break. *Lab Med*. 1999;30:710; 5) Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition*. CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**GEN.72600**

**Phase II**

**N/A YES NO**

**Are gloves provided, readily available and mandatory for use by phlebotomists? (Exception: voluntary blood donor centers.)**

*NOTE: 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.*

**COMMENTARY:**

N/A

**REFERENCES:** 1) Murray RL. Keep wearing your gloves. *Med Lab Observ*. 1994(Mar):80; 2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 3) Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition*. CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

**GEN.72650****Phase II****N/A YES NO**

**Have all personnel been instructed in the proper use and care of disposable gloves, and the need for hand decontamination after glove removal?**

*NOTE: The required elements of education include:*

1. *Properly fitting gloves*
2. *Replacing gloves immediately when torn or contaminated*
3. *Not washing or disinfecting gloves for reuse*
4. *Using hypoallergenic gloves when indicated by patient or healthcare provider history*
5. *Decontamination of hands after glove removal*

*To prevent the transmission of potentially infectious agents, OSHA requires handwashing or antiseptics after glove removal. The CDC has published guidelines for hand hygiene. If hands are visibly dirty or contaminated with blood or proteinaceous material, the CDC recommends that the individual wash their hands with soap and water. If hands are not visibly soiled, an alcohol-based waterless agent may be used for routinely decontaminating hands.*

COMMENTARY:

N/A

REFERENCES: 1) Murray RL. Keep wearing your gloves. *Med Lab Observ.* 1994(Mar):80; 2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1):[29CFR1910.1030].

**GEN.72700****Phase II****N/A YES NO**

**Do 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.*

COMMENTARY:

N/A

REFERENCE: NCCLS. *Clinical Laboratory Safety; Approved Guideline—Second Edition.* NCCLS document GP17-A2 (ISBN 1-56238-530-5). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.





**GEN.72900**

**Phase II**

**N/A YES NO**

**Are vacuum breakers (anti-siphon devices) provided on water outlets where necessary?**

*NOTE: This is necessary only if the spigot or an extension extends below sink level, or if the outlet has a suction apparatus attached.*

COMMENTARY:

N/A

REFERENCE: Woodruff PH. Prevention of contamination of drinking water supplies, In Handbook of laboratory safety. Boca Raton, FL: CRC Press, 1978.

**GEN.72950**

**Phase II**

**N/A YES NO**

**For U.S. laboratories, do 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**
- 3. Code of Federal Regulations. Title 29, part 1910.1450 and its appendices**

*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.*

COMMENTARY:

N/A

**GEN.73000**

**Phase II**

**N/A YES NO**

**Are all infectious wastes (e.g., glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse 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.*

COMMENTARY:

N/A

REFERENCES: 1) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 2) NCCLS. Clinical laboratory waste management; approved guideline-second edition; approved guideline GP5-A2. Wayne, PA: NCCLS, 2002.

**GEN.73050 Phase II N/A YES NO**

**Are all corrosive, ignitable, and toxic wastes disposed of safely in labeled containers?**

COMMENTARY:

N/A

REFERENCE: NCCLS. Clinical laboratory waste management; approved guideline-second edition; approved guideline GP5-A2. Wayne, PA: NCCLS, 2002.

**GEN.73100 Phase II N/A YES NO**

**Are sterile syringes, needles, lancets, or other blood-letting devices ("sharps") that are capable of transmitting infection used once only, and are all waste sharps 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 U.S. 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.*

COMMENTARY:

N/A

REFERENCES: 1) Bush VJ, et al. Advancements in blood collection devices. *Lab Med.* 1998;29:616-622; 2) Dale JC, et al. Accidental needlesticks in the phlebotomy service of the department of laboratory medicine and pathology at Mayo Clinic Rochester. *Mayo Clin Proc.* 1998;73:611-615; 3) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030]; 4) Occupational Safety and Health Administration. Enforcement procedures for the occupational exposure to bloodborne pathogens. Washington, DC: U.S. Government Printing Office, OSHA Directive CPL 2-2.44D, 1999 (Nov 5); 5) NCCLS. Clinical laboratory waste management; approved guideline-second edition; approved guideline GP5-A2. Wayne, PA: NCCLS, 2002.