



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
 4/6/2006 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.12000	04/06/2006
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
GEN.41316	10/06/2005
GEN.41470	10/06/2005
GEN.43878	10/06/2005
GEN.43881	10/06/2005
GEN.43884	10/06/2005
GEN.43887	10/06/2005
GEN.43890	10/06/2005
GEN.43893	10/06/2005
GEN.61750	10/06/2005
GEN.66100	10/06/2005
GEN.20262	03/30/2005
GEN.40492	03/30/2005
GEN.40497	03/30/2005
GEN.40498	03/30/2005
GEN.40932	03/30/2005
GEN.40967	03/30/2005
GEN.40992	03/30/2005
GEN.41017	03/30/2005
GEN.41042	03/30/2005
GEN.42975	03/30/2005
GEN.43011	03/30/2005

GEN.43033	03/30/2005
GEN.43099	03/30/2005
GEN.43121	03/30/2005
GEN.43262	03/30/2005
GEN.43387	03/30/2005
GEN.43812	03/30/2005
GEN.43933	03/30/2005
GEN.48750	03/30/2005
GEN.20365	12/29/2004
GEN.20366	12/29/2004
GEN.20370	12/29/2004
GEN.20371	12/29/2004

REVISED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
GEN.20375	04/06/2006
GEN.20377	04/06/2006
GEN.41320	04/06/2006
GEN.41340	04/06/2006
GEN.53400	04/06/2006
GEN.71000	04/06/2006
GEN.71450	10/06/2005
GEN.41067	03/30/2005
GEN.41304	03/30/2005
GEN.42165	03/30/2005
GEN.42900	03/30/2005
GEN.43077	03/30/2005
GEN.43200	03/30/2005
GEN.43450	03/30/2005
GEN.55500	03/30/2005
GEN.16902	12/29/2004
GEN.20332	12/29/2004
GEN.20348	12/29/2004
GEN.20364	12/29/2004

DELETED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
GEN.30050	04/06/2006
GEN.50000	10/06/2005
GEN.50100	10/06/2005
GEN.50300	10/06/2005
GEN.50400	10/06/2005

GEN.50500	10/06/2005
GEN.50600	10/06/2005
GEN.50700	10/06/2005
GEN.50800	10/06/2005
GEN.50900	10/06/2005
GEN.51000	10/06/2005
GEN.51100	10/06/2005
GEN.51325	10/06/2005
GEN.51550	10/06/2005
GEN.51775	10/06/2005
GEN.52000	10/06/2005
GEN.52033	10/06/2005
GEN.52066	10/06/2005
GEN.52100	10/06/2005
GEN.52200	10/06/2005
GEN.53300	10/06/2005
GEN.53350	10/06/2005
GEN.44050	03/30/2005

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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 values*
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.

INSPECTION TECHNIQUES – KEY POINTS

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 were unable to find a 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 values 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.

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):7146 [42CFR493.1236(c)(1)]; 2) Laessig RH, Ehrmeyer SS. Proficiency testing. Then, now, and in the future. *Clin Lab News*. 1999;25(7):18-20; 3) NCCLS. *Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline*. NCCLS document GP29-A [ISBN 1-56238-479-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

GEN.11226

Phase II

N/A YES NO

Does the laboratory have a procedure for assessing its performance on PT challenges that were not graded because of lack of consensus, or because the laboratory submitted its results after the cut-off date for receipt, did not submit results, or made an error in completing the result form?

NOTE: This question addresses PT challenges that were intended to be graded, but were not, for reasons such as: 1) lack of consensus, 2) the laboratory submitted its results after the cut-off date, 3) the laboratory did not submit results, 4) the laboratory did not complete the result form correctly (for example, submitting the wrong method code or recording the result in the wrong place). 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).

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.11484

Phase II

N/A YES NO

Are records of all proficiency testing and alternative performance assessments since the last on-site inspection complete?

NOTE: Records must include worksheets, instrument tapes, reporting forms, evaluation reports, participant summaries, and documentation of follow-up, as applicable.

COMMENTARY:

N/A

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)].

QUALITY MANAGEMENT

The laboratory must have a documented quality management program to systematically evaluate the quality and appropriateness of laboratory services. The program must be designed to identify and resolve important problems in patient care, and identify opportunities to improve patient care. 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.

Analytic quality control (QC), although a part of quality management, is addressed in a separate section of this checklist.

GEN.13806**Phase II****N/A YES NO**

Does the quality management (QM) program follow a documented operational plan?

NOTE: There must be a document, approved by the laboratory director, that describes the overall QM program. This plan may be based upon some reference resource such as NCCLS GP-22 or GP-26, the ISO 9000 series, JCAHO's model for improving organizational performance, AABB's quality program, or it may be of the laboratory's own design. The purpose of this document is to spell out the goals and objectives of the QM program. The document need not be detailed, but it should itemize the essential aspects of the program. The QM plan should address the current CAP patient safety goals. The laboratory should be able to use this document for guidance in its annual appraisal of effectiveness.

COMMENTARY:

N/A

REFERENCES: 1) Bachner P. College of American Pathologists conference XVII on quality assurance in pathology and laboratory medicine: summary. *Arch Pathol Lab Med.* 1990;114:1175-1177; 2) Bozzo P. Implementing quality assurance. Chicago: American Society of Clinical Pathologists Press, 1991:33-58; 3) Kritchevsky SB, Simmons BP. Continuous quality improvement. Concepts and applications for physician care. *JAMA.* 1991;266:1817-1823; 4) Bozzo PD. Conducting QI studies that effect change. *Med Lab Observ.* 1992(Oct):39-42; 5) Goodnough LT, et al. Economic impact of inappropriate blood transfusions in coronary artery bypass graft surgery. *Am J Med.* 1993;94:509-514; 6) Joint Commission on Accreditation of Healthcare Organizations. Framework for improving performance: from principles to practice. Oakbrook Terrace, IL: JCAHO, 1994; 7) ISO Standards compendium: ISO 9000 quality management, 6th ed. Geneva, Switzerland: International Organization for Standardization, 1996; 8) Berte LM. Tools for improving quality in the transfusion service. *Am J Clin Pathol.* 1997;107(suppl 1):S36-S42; 9) Connelly DP, Aller RD. Outcomes and informatics. *Arch Pathol Lab Med.* 1997;121:1176-1182; 10) NCCLS. A quality system model for healthcare; proposed guideline GP26-P. Wayne, PA: NCCLS, 1998; 11) NCCLS. Continuous quality improvement: essential management approaches; approved guideline GP22-A. Wayne, PA: NCCLS, 1998; 12) College of American Pathologists, Commission on Laboratory Accreditation. Standards for laboratory accreditation; standard III. Northfield, IL: CAP, 1998; 13) Hamlin WB. Requirements for accreditation by the College of American Pathologists laboratory accreditation program. *Arch Pathol Lab Med.* 1999;123:465-467; 14) Nevalainen DE. ISO 9000: quality systems and accreditation. *Lab Med.* 1999;30:732-735; 15) Bachner P. Patient outcomes and pathology practice. An introduction to the College of American Pathologists conference XXXIV on molecular pathology: role in improving patient outcome. *Arch Pathol Lab Med.* 1999;123:996-999; 16) Galloway M, Nadin L. Benchmarking and the clinical laboratory. *J Clin Pathol.* 2001;54:590-597;

COMMENTARY:

N/A

GEN.20208**Phase II****N/A YES NO****Does the QM system include an on-going 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).

****NEW******03/30/2005****GEN.20262****Phase I****N/A YES NO****Does the laboratory review and assess its records of errors and incident reports at defined intervals to identify trends and initiate corrective/preventive actions as appropriate?**

NOTE: Investigation of individual problems may not reveal trends or patterns caused by underlying system problem(s). Thus, the laboratory should periodically group errors and incident reports together for review, to detect system problem(s) that could be responsible for some errors or incidents.

COMMENTARY:

N/A

GEN.20316

Phase II

N/A YES NO

Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement?

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 values with documentation that values 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 25th percentile (i.e., 75% or more of the other laboratories in the study perform better). Use of the indicators listed above does not require enrollment in any quality monitoring product.

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.

****REVISED**** **12/29/2004**

GEN.20332 **Phase II** **N/A YES NO**

Are appropriate corrective and/or preventive actions taken when opportunities for improvement are identified?

COMMENTARY:

N/A

****REVISED**** **12/29/2004****GEN.20348****Phase II****N/A YES NO****Are preanalytic variables 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. This list is neither all-inclusive nor exclusive. 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.

****REVISED**** **12/29/2004****GEN.20364** **Phase II** **N/A YES NO****Are postanalytic variables 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.

****NEW**** **04/06/2006****GEN.20365** **Phase II** **N/A YES NO****Does the laboratory address the current CAP Laboratory Patient Safety Goals?**

NOTE: The current CAP Laboratory Patient Safety Goals are: 1) Improve patient and sample identification at specimen collection, analysis and resulting; 2) Improve verification and communication of life-threatening or life-altering information regarding malignancies, HIV (and other serious infectious diseases), cytogenetic abnormalities, and critical values; 3) Improve identification, communication and correction of errors in a timely manner; 4) Improve the coordination of the laboratory's patient safety role within healthcare organizations. The laboratory must document that these goals have been addressed by evaluation and/or monitoring of the processes involved.

COMMENTARY:

****NEW******12/29/2004****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.

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/mdr-general.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

****NEW**** **12/29/2004**

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>.

COMMENTARY:

N/A

****NEW**** **10/06/2005**

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

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. Current paper copies of electronically stored procedures should be available at the time of the CAP inspection, or rapidly generated at the request of the inspector.

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) NCCLS. Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition. NCCLS document GP2-A4 (ISBN 1-56238-458-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2002; 2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003.

GEN.20376

Phase I

N/A YES NO

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

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition. NCCLS document GP2-A4 (ISBN 1-56238-458-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA 2002; 2) ISO International Standard 15189: Medical laboratories—Particular requirements for quality and competence. Geneva: International Organization for Standardization, 2003.

****REVISED**** **04/06/2006****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 microbiology slides 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 transmitted by computer 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 entry of patient result data requires that all worksheets, print-outs, etc. are retained by the laboratory for at least two years.

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.20380

Phase I

N/A YES NO

Are graphical tools (charts and graphs) used to communicate quality findings?

NOTE: Use of graphical displays, in addition to indicating that the laboratory has done something with the data, communicates information more effectively than tables of numbers. Examples of graphical tools commonly used for this purpose include Pareto charts, cause-and-effect (fishbone) diagrams, frequency histograms, trend graphs, force-field analyses, and flow charts. Effective communication is an essential element of a QM plan.

COMMENTARY:

N/A

REFERENCES: 1) Westgard JO, Barry PL. Total quality control: evaluation of quality management systems. *Lab Med.* 1989;20:377-384; 2) Westgard JO, *et al.* Implementing total quality management (TQM) in healthcare laboratories. *Clin Lab Med Rev.* 1991;5:353-370; 3) Simpson KN, *et al.* Total quality and the management of laboratories. *Clin Lab Med Rev.* 1991;5:448-462; 4) Joint Commission on Accreditation of Healthcare Organizations. The transition from QA to CQI: an introduction to quality improvement in health care. Oakbrook, IL: JCAHO, 1991; 5) Clark GB. Systematic quality management. Chicago, IL: American Society of Clinical Pathologists Press, 1995; 6) Carey RG, Lloyd RC. Measuring quality improvement in healthcare. A guide to statistical process control applications. New York, NY: Quality Resources Publishing, 1995; 7) Nevalainen D, *et al.* Evaluating laboratory performance on quality indicators with the six sigma scale. *Arch Pathol Lab Med.* 2000;124:516-519; 8) Tufte ER. The Visual Display of quantitative Information. Second edition. Cheshire, CT: Graphics Press, 2001.

QUALITY CONTROL

The overall quality control program for the entire laboratory must be clearly documented. It must include general policies and delegation of responsibilities. The quality control records should be well-organized with a system to permit regular review by appropriate supervisory personnel (laboratory director, supervisor or laboratory quality control coordinator).

GEN.30000

Phase II

N/A YES NO

Is there a written quality control program that clearly defines procedures for monitoring analytic performance, including establishment of tolerance limits, number and frequency of controls, corrective actions based on quality control data, and related information?

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

GEN.30200 **Phase II**

N/A YES NO

Are quality control records retained for at least 2 years?

COMMENTARY:

N/A

GEN.30300 **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

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)].

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.

GEN.40470**Phase I****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 - fourth edition; approved standard H3-A4. Wayne, PA: NCCLS, 1998; 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.

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

Does the specimen collector positively identify the patient before collecting a specimen?

NOTE: The exact manner in which hospitals and independent laboratories meet this requirement may vary. In the hospital, personnel must confirm the patient's identity by checking at least two identifiers before collecting a specimen. For example, the patient's wristband may be checked for name and unique hospital number. The patient's room number may not be used as an identifier. For outpatients drawn in hospital or independent laboratories, asking the patient's name may be sufficient. The intent of this question is to ensure a documented, consistently followed system for correct patient sample identification from point of collection through all phases of specimen movement through the laboratory. The identifying label must be attached to the specimen container(s) at the time of collection, and not deferred until a later time.

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 - fourth edition; approved standard H3-A4. Wayne, PA: NCCLS, 1998; 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.

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.

COMMENTARY:

N/A

REFERENCES: 1) NCCLS. Evacuated tubes for blood specimen collection - fourth edition; approved standard H1-A4. Wayne, PA: NCCLS, 1996; 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 - fourth edition; approved standard H3-A4. Wayne, PA: NCCLS, 1998; 4) NCCLS. Laboratory automation: bar codes for specimen container identification; proposed standard AUTO2-P. Wayne, PA: NCCLS, 1998.

****NEW****

03/30/2005

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

****NEW******03/30/2005****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.

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.

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

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

NOTE: Federal and international regulations mandate the proper packaging and transportation of infectious substances, also termed "etiologic agents." 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) 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; 6) <http://www.iata.org/dangerousgoods/index>; 7) <http://www.phppo.cdc.gov/nltn/default.aspx>.

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

REQUISITIONS AND SPECIMEN RECEIPT/HANDLING/ASSESSMENT

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

GEN.40825**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: NCCLS. Laboratory automation: bar codes for specimen container identification; proposed standard AUTO2-P. Wayne, PA: NCCLS, 1998.

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.

NEW

03/30/2005

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 must read back the entire order to verify accuracy of transcription?

COMMENTARY:

N/A

GEN.40942

Phase I

N/A YES NO

Has the laboratory evaluated its specimen containers to ensure that they do not contribute to analytic interference in the assays to be performed?

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

COMMENTARY:

N/A

REFERENCES: 1) Herr RD, Swanson RT. Pseudometabolic acidosis caused by underfill of Vacutainer tubes. *Ann Emerg Med.* 1992;21:177-180; 2) Pewarchuk W, *et al.* Pseudopolycythemia, pseudothrombocytopenia, and pseudoleukopenia due to overfilling of blood collection tubes. *Arch Pathol Lab Med.* 1992;116:90-92; 3) Bartlett WA, *et al.* Vacutainer system can lead to inaccurate results. *Brit Med J.* 1993;307:868; 4) Banfi G. State of the art of preanalysis in laboratories in Italy performing endocrinologic tests. *Eur J Clin Chem Clin Biochem.* 1995;33:99-101; 5) Bonini PA, *et al.* "La fase preanalitica" bibliografia. *Biochem Clin.* 1995;19:206-216; 6) Newman RS, Fagin AR. Heparin contamination in coagulation testing and a protocol to avoid it and the risk of inappropriate FFP transfusion. *Am J Clin Pathol.* 1995;104:447-449; 7) Kallner A. Preanalytical procedures in the measurement of ionized calcium in serum and plasma. *Eur J Clin Chem Clin Biochem.* 1996;34:53-58; 8) Farkas DH, *et al.* Specimen collection and storage for diagnostic molecular pathology investigation. *Arch Pathol Lab Med.* 1996;120:591-596; 9) Wenk RE. Disposables as sources of preanalytical contamination and misdiagnosis. *Am J Clin Pathol.* 1997;107:395-397; 10) Dasgupta A, *et al.* Stability of therapeutic drug measurement in specimens collected in Vacutainer plastic blood-collection tubes. *Ther Drug Monit.* 1996;18:306-309; 11) Li W, *et al.* Adsorption of tricyclic antidepressants to arylac and polyester separator gels in blood collection tubes. *Clin Chem.* 1996;42:S224; 12) Sampson M, *et al.* Positive interference in lithium determinations from clot 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.

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: The address of an outside reference laboratory may be on the report, or available in other records from the reporting laboratory. 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. The address of the reporting laboratory should be on the report.

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**** **03/30/2005**

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?

NOTE: U.S. laboratories must have procedures to ensure compliance with The Health Information Portability and Accountability Act (HIPAA).

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)].

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

****NEW**** **10/06/2005**

GEN.41316 **Phase I** **N/A YES NO**

Is there a policy regarding the timely communication, and documentation thereof, of new diagnoses of human immunodeficiency virus infection, and other infectious diseases of particular significance?

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.

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 values are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. These values 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 values?

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**** **04/06/2006**

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

Does the laboratory have a policy with respect to a verification “read-back” of critical results that are communicated verbally or by phone?

NOTE: 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*
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)].

QUALITY OF WATER AND GLASSWARE WASHING

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. Reagent grades, as defined by the NCCLS Guideline C3-A3 include the following specifications at time of production:

	Type I	Type II	Type III
Maximum microbial content (CFU/mL)	10	1000	n/a
Minimum resistivity (megohm-cm)	10 (in-line)	1.0	0.1
Maximum silicate content (mg/L SiO ₂)	0.05	0.1	1.0
Particulate matter	0.22 um filter	n/a	n/a

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. Silicates or colloidal silica may interfere with certain assays.

The NCCLS Guideline provides testing information for microbial content, resistivity, and silicates. It also 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. NCCLS information is provided herein as a convenient guide to laboratories, and does not necessarily represent CAP standards or requirements.

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 should include resistivity and microbiology cultures. Silicate testing should be done initially to determine if high concentrations are present in the source water. Other criteria, such as pH, particulate matter, endotoxin/pyrogens, and organic contaminants are at the discretion of the laboratory.

Typically, "sterile (pharmaceutical) water" is not manufactured to meet the specifications of reagent water, and should not be used as its equivalent.

For commercial instrument-reagent systems, the laboratory may use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with Type I or lower 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) NCCLS. Preparation and testing of reagent water in the clinical laboratory - third edition; approved guideline C3-A3. Wayne, PA: NCCLS, 1997; 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) NCCLS. Preparation and testing of reagent water in the clinical laboratory - third edition; approved guideline C3-A3. Wayne, PA: NCCLS, 1997; 2) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med*. 2000;31:605-611.

GEN.41650**Phase I****N/A YES NO**

Has the laboratory evaluated its source water to determine if a high concentration of silicates is present?

NOTE: Soluble or colloidal silica in the source water is a major problem in certain geographical locations and may not be adequately removed with some purification processes. Silica concentrations greater than 0.05 mg/L (measured as SiO₂) may interfere with certain assays. The reference provides detailed steps for testing with molybdate ion and 1-amino-2-naphthol-4-sulfonic acid.

COMMENTARY:

N/A

REFERENCES: 1) Gabler R, *et al.* Degradation of high-purity water on storage. *J Liquid Chromatogr*. 1983;6:2565-2570; 2) NCCLS. Preparation and testing of reagent water in the clinical laboratory - third edition; approved guideline C3-A3. Wayne, PA: NCCLS, 1997; 3) Stewart BM. The production of high-purity water in the clinical laboratory. *Lab Med*. 2000;31:605-611.

- 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, CaCl₂) 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>).

TEST METHOD VALIDATION

METHOD PERFORMANCE SPECIFICATIONS

Sound laboratory practice requires full characterization of an assay before its use for patient testing, irrespective of federally-designated test complexity and without regard to when it 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) NCCLS. *Statistical quality control for quantitative measurements: principles and definitions - second edition; approved guideline C24-A2*. Wayne, PA: NCCLS, 1998; 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.

LABORATORY COMPUTER SERVICES

Multiple solutions for laboratory information systems (LIS) exist. Traditional systems have a local "host" database (i.e., the computer hardware and software) serving the information needs of the laboratory; the laboratory is the only "user." In the current environment, the host is often physically remote from the laboratory and in fact the host may have multiple user laboratories. Many of the Computer Services 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

****REVISED**** 03/30/2005

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

****REVISED**** *03/30/2005*

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.

COMMENTARY:

N/A

LIS/COMPUTER PROCEDURE MANUAL

GEN.42950 **Phase II** **N/A YES NO**

Are LIS/computer procedures clearly documented, complete and readily available to all authorized users?

NOTE: Procedures should be appropriate to the level of use of the system, and must encompass the day-to-day activities of the laboratory staff as well as the daily operations of the Information Technology staff. It is not required for all procedures to be kept in a single manual, as long as the users have access to the procedures they need to perform their job duties. Current practice must match policy and procedure documents.

COMMENTARY:

N/A

****NEW**** *03/30/2005*

GEN.42975 **Phase II** **N/A YES NO**

Is there a procedure for the support of the computer system?

NOTE: The laboratory must have a procedure outlining the support of the system, including local maintenance, vendor support and emergency contact information.

COMMENTARY:

N/A

GEN.43000

Phase II

N/A YES NO

Is there documentation that laboratory computer procedures are reviewed at least annually by the laboratory director or designee?

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

COMMENTARY:

N/A

HARDWARE AND SOFTWARE

****NEW****

03/30/2005

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

GEN.43132 Phase II

N/A YES NO

Is there evidence of ongoing evaluation of system maintenance records?

NOTE: Hardware manufacturers have a standard maintenance schedule that must be documented, similar to laboratory instrument maintenance. In addition, regularly scheduled maintenance must be documented for printers (cleaning, other service records).

COMMENTARY:

N/A

SYSTEM SECURITY

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

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

****REVISED** 03/30/2005**

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

****NEW****

03/30/2005

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

GEN.44100

Phase II

N/A YES NO

Are computer error messages that alert computer users of imminent problems monitored and is the error message response system tested periodically?

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. The error message response process needs to be periodically tested.

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.

INTERFACES

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.

NETWORKS

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

PERSONNEL

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

TECHNICAL SUPERVISOR

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. 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, mark all questions in this subsection "N/A" and continue with the GENERAL SUPERVISOR subsection.

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

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

GEN.53400 **Phase II** **N/A YES NO**

Does the technical supervisor 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. If the technical supervisor is responsible for anatomic pathology then he/she must be certified in anatomic pathology or possess qualifications equivalent to those required for certification. If the technical supervisor is responsible for clinical pathology then he/she must be certified in clinical pathology or possess qualifications equivalent to those required for certification. If the technical supervisor is responsible for both areas, 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 the 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].

GENERAL SUPERVISOR

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. 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, mark all questions in this subsection "N/A" and continue with the ALL PERSONNEL subsection.

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

Does the general supervisor 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

Does the general supervisor 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

N/A

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 verification for laboratory personnel; approved guideline GP21-A. Wayne, PA: NCCLS, 1996.

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 verification for laboratory personnel; approved guideline GP21-A. Wayne, PA: NCCLS, 1996; 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

REFERENCE: Fetter MC. Colorimetric tests read by color-blind people. *Am J Med Technol.* 1963;349-355.

****REVISED**** **03/30/2005**

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 that an individual tests patient specimens, competency must be assessed at least every six months. Retraining and reassessment of employee competency must occur when problems are identified with employee performance. Competency assessment for each individual must include all of the following elements that are applicable to the individual's duties:

1. *Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing*
2. *Monitoring the recording and reporting of test 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*

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 verification for laboratory personnel; approved guideline GP21-A. Wayne, PA: NCCLS, 1996; 5) Blackledge L. Professional perspectives.

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

POWER

****NEW****

10/06/2005

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

LABORATORY SAFETY

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.

N/A

GEN.70032 **Phase II** **N/A YES NO**

Does the director or designee review and approve all changes to the safety policies and procedures before implementation?

COMMENTARY:

N/A

GEN.70050 **Phase II** **N/A YES NO**

Have policies and procedures been developed regarding the documentation of all laboratory accidents resulting in property damage or involving spillage of hazardous substances?

COMMENTARY:

N/A

GEN.70100 **Phase II** **N/A YES NO**

Have policies and procedures been developed regarding the reporting of all occupational injuries or illnesses that require medical treatment (except first aid)?

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 GP17-A. Wayne, PA: NCCLS, 1996; 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:A4-6.3.1 Quincy, MA: NFPA, 2000; 3) National Fire Protection Association. Standard 99, chapter 10-2.2.4.3. Quincy, MA: NFPA, 2000.

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 GP17-A. Wayne, PA: NCCLS, 1996; 4) National Fire Protection Association. NFPA 10 - Standard for portable fire extinguishers. Quincy, MA: NFPA, 1990; 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 GP17-A. Wayne, PA: NCCLS, 1996.

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: The Environmental Protection Agency (EPA) and the American Hospital Association have recently announced an agreement on mercury reduction, with the goal of eliminating mercury from hospitals by the year 2005. 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

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)*
6. *Eliminating the practice of disposing non-hazardous waste in hazardous waste containers*

The goal should be to generate less hazardous waste each year than was generated in the preceding year. This may not always be achievable, but accredited laboratories are urged to make this effort.

COMMENTARY:

N/A

REFERENCES: 1) Hazardous solid wastes amendments act, 1984: Public law 98-616; 2) Wenk PA. Disposal of histology stains. *Lab Med.* 1998;29:337-338; 3) Ornelas D, *et al.* The laboratory's role in reducing hazardous waste. *Lab Med.* 1998;29:287-290; 4) Ornelas D, *et al.* The role of recycling and chemical substitution in pollution prevention programs. *Lab Med.* 1998;29:356-359; 5) Brzezicki LA. Managing your materials. *Advance/Lab.* 1999;8(6):123-127; 6) NCCLS. Clinical laboratory waste management; approved guideline-second edition; approved guideline GP5-A2. Wayne, PA: NCCLS, 2002.

GEN.70750**Phase II****N/A YES NO****Are policies and procedures documented and adequate for internal and external disaster preparedness?**

COMMENTARY:

N/A

GEN.70800

Phase II

N/A YES NO

Is there a comprehensive, documented and workable evacuation plan for the laboratory, including specific plans for any persons with disabilities?

NOTE: This plan must cover all employees, patients and visitors, and should address the special needs of persons with disabilities. Evacuation routes must be posted.

COMMENTARY:

N/A

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

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.

GEN.70832**Phase II****N/A YES NO****Are policies documented to prevent or reduce ultraviolet light exposure from instrument sources?**

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

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

COMMENTARY:

N/A

REFERENCES: 1) Fleming DO, *et al.* Laboratory safety. Principles and practices, 2nd ed. Washington, DC: American Society for Microbiology, 1995; 2)
<http://www.cdc.gov/niosh/hcwold5e.html>.

GEN.70850**Phase II****N/A YES NO****Are policies and procedures documented and adequate for radiation safety?**

COMMENTARY:

N/A

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

GEN.70900

Phase II

N/A YES NO

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

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

COMMENTARY:

N/A

REFERENCES: 1) Glass EC, *et al.* Editorial: radiation safety considerations for sentinel node techniques. *Ann Surg Oncol.* 1999;6:1; 2) Miner TJ, *et al.* Guideline for the safe use of radioactive materials during localization and resection of sentinel lymph nodes. *Ann Surg Oncol.* 1999;6:75-8; 3) 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) NCCLS. Protection of laboratory workers from occupationally acquired infections; approved guideline M29-A2. Wayne, PA: NCCLS, 2002.

****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) NCCLS. Protection of laboratory workers from occupationally acquired infections; approved guideline M29-A2. Wayne, PA: NCCLS, 2002.

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 GP17-A. Wayne, PA: NCCLS, 1996; 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) Vandenplas O, *et al.* Latex gloves with a lower protein content reduce bronchial reactions in subjects with occupational asthma caused by latex. *Am J Respir Crit Care Med*. 1995;151:887-891; 10) Thomson CM. The potential risks of latex. *Brit Med J*. 1996;6(5):12-14; 11) Ownby DR, *et al.* The prevalence of anti-latex IgE antibodies in 1000 volunteer blood donors. *J Allergy Clin Immunol*. 1996;97:1188-1192; 12) Kaczmarek RG, *et al.* Prevalence of latex-specific IgE antibodies in hospital personnel. *Allergy Asthma Immunol*. 1996;76:51-56; 13) Liss GM, *et al.* Latex allergy: epidemiological study of 1351 hospital workers. *Occup Environ Med*. 1997;54:335-342; 14) Leung R, *et al.* Prevalence of latex allergy in hospital staff in Hong Kong. *Clin Exp Allergy*. 1997;27:167-174; 15) The National Institute for Occupational Safety and Health (NIOSH). Alert. Preventing allergic reactions to natural rubber latex in the workplace. Washington, DC: DHHS publication 97-135, Jun 1997; 16) Sussman GL, *et al.* Incidence of latex sensitization among latex glove users. *J Allergy Clin Immunol*. 1998;101:171-178; 17) Sainato D. The irritation of latex allergy. Labs should be aware of causes and solutions. *Clin Chem News*. 1999;25(7):1-10; 18) Graves PB. Latex allergy: a laboratory view. *Amer Clin Lab*. 2000;19(2):16-1; 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 GP17-A. Wayne, PA: NCCLS, 1996; 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) NCCLS. Protection of laboratory workers from occupationally acquired infections; approved guideline M29-A2. Wayne, PA: NCCLS, 2002.

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. Standard 99, chapter 10-8. Quincy, MA: NFPA, 2000.

****REVISED**** 10/06/2005

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

PHYSICAL INSPECTION OF THE LABORATORY

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: 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. Standard 99, chapter 10-5.2. Quincy, MA: NFPA, 2000.

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. Standard 45, chapter 4-5.4. Quincy, MA: NFPA, 2000; 3) National Fire Protection Association. Standard 99, chapter 10-5.2. Quincy, MA: NFPA, 2000.

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. Standard 45, chapter 4-5.4. Quincy, MA: NFPA, 2000; 3) National Fire Protection Association. Standard 99, chapter 10-5.2. Quincy, MA: NFPA, 2000.

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) Joint Commission on Accreditation of Healthcare Organization. Plant, technology and safety management series, standard EC.2.13. Chicago, IL: JCAHO, 1996; 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. Flammable and combustible liquids code. Standard 30, chapter 10-2.2.4.3. Quincy, MA: NFPA, 1996.

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 ft² of space defined by fire-resistant walls/doors. Up to 2 gallons of Class I, II, and IIIA liquids may be stored in safety cans and safety cabinets for each 100 ft². These amounts may be doubled if there is an automatic fire suppression system (e.g., sprinklers).

GEN.72550**Phase II****N/A YES NO**

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

NOTE: 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) NCCLS. Protection of laboratory workers from occupationally acquired infections; approved guideline M29-A2. Wayne, PA: NCCLS, 2002.

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) NCCLS. Protection

of laboratory workers from occupationally acquired infections; approved guideline M29-A2. Wayne, PA: NCCLS, 2002.

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 antisepsis 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 GP17-A. Wayne, PA: NCCLS, 1996.

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.