College of American Pathologists
Laboratory Accreditation Program

Checklist Updates

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January 16, 2008
Learning Objectives

- As a result of participating in this activity, you will be able to:
  - Describe revisions to the following checklists or topics: transfusion medicine, microbiology, water quality, proficiency testing, and technical consultant requirements.
  - Apply updated checklist requirements in the following areas to your own preparation efforts: method performance specifications, single use devices, built-in (internal) controls, CAP Patient Safety Goals, critical results, and document control.
CAP Web Site Checklist Information

• Current and most previous edition for each checklist
• Change document for each checklist showing revisions since previous editions
  – New checklist questions
  – Revised questions
  – Deleted questions
  – “Migrated” questions
• List of new, deleted and revised questions at beginning of each checklist, with date of change (items on list for 18 mos.)
• Most frequently cited deficiencies
  – Most recent period, 2005 – 2006
• Summary of revisions to current checklist edition
Administrative Requirements: “Terms of Accreditation”

Revisions for 2007 edition:

**GEN.26791 Phase II**

**Does the laboratory have a policy that addresses compliance with the CAP terms of accreditation?**

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

1. **Investigation of the laboratory by a government entity or adverse media attention related to laboratory performance; notification must occur no later than 2 working days** after the laboratory learns of an investigation or adverse media attention

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

3. **Change in location, ownership or directorship of the laboratory; notification must occur prior to the change(s); or, in the case of unexpected changes, no later than 2 working days afterwards**
Checklist “Freeze” in 2007 – 8

• As condition of an accreditation organization’s deemed status under CLIA-88, CMS is required to evaluate the organization’s requirements at a maximum interval of every 6 years to assure that stringency is at least equal to CLIA-88 regulations (42CFR493.553(c)).

• CAP was first full-service accreditor to be given full 6-year approval
Checklist “Freeze” in 2007 – 8

• History of CAP Deemed Status
  – 1995: First granted deemed status
  – 1999: Deemed status continued following second CMS review of checklists…
    • CMS does not permit revisions during review period; checklists “frozen” for 2.5 years, until CMS approval granted 2001
  – 2007 Third CMS evaluation
    September 2007 checklist edition submitted to CMS…anticipate “freeze” of 12 – 18 months
Review of Method Performance Specifications (Quantitative Tests)

- Accuracy
- Precision
- Analytic sensitivity (lower limit of detection)
- Analytic specificity (interferences)
- Reportable range (analytic measurement range (AMR); may be extended by dilution to a “clinically reportable range (CRR)”)
- Reference range
Review of Method Performance Specifications

• CAP Requirements (in GEN – Test Method Validation Section)
  – Similar, but not identical to CLIA-88
  – Applicable to all non-waived tests regardless of date of introduction
  – Fundamental distinction
    • FDA cleared/approved tests vs other tests
Review of Method Performance Specifications

CAP Requirements (in GEN – Test Method Validation Section), cont.

- Accuracy and precision
  - FDA cleared – verify manufacturer data
  - Other tests – establish
- Analytic sensitivity
  - FDA cleared – use manufacturer or literature data
  - Other tests – establish
- Analytic specificity
  - FDA cleared – use manufacturer or literature data
  - Other tests – establish or use manufacturer/literature data
- Reportable range
  - Establish or verify information from literature or manufacturer
- Reference range
  - Establish, verify, or use manufacturer information or literature, as appropriate
- Retention of records of MPS
  - 2 yrs after discontinuation of method
Review of Method
Performance Specifications

• Laboratories Not Subject to CLIA-88
  – Must establish or verify MPS as appropriate
  – May use data from literature or manufacturer but should verify when practical
Single Use Devices

• Must MPS be established/verified for every reader?
  – For every reader, laboratory must:
    • Verify (initially) accuracy, precision, reportable range
  – For analytic sensitivity and specificity, data from literature/manufacturer may be used
  – For reference range, literature/manufacturer data may be verified (when possible) on a subset of readers
Single Use Devices

- Calibration
  - Perform on **all** readers (generally these devices self-calibrate)
- Calibration verification, if applicable
  - Perform on **all** readers
- Interinstrument comparison
  - Subset of readers
- AMR validation
  - Subset of readers
- Validation of new lots/shipments of reagents/cartridges
  - Subset of readers
- PT
  - Subset of readers
- Validation of built-in QC systems
  - Subset of readers
- Rotate the subset used for interinstrument comparison, AMR validation, new reagent/cartridge lots, PT
Single Use Devices

• Refer to:
  – POC.05000 – Reagents
  – POC.07568 – Interinstrument comparisons
  – POC.08050, 08100, 08200 – Calibration
  – POC.08300, 08400 - Calibration verification
  – POC.08450, 08500, 08600, 08650 – AMR
POC

• PPT section (physician-performed testing; changed to *provider* performed testing, Sept 2007)
  – In Sept 2007 edition, extended to include mid-level practitioners (physician assistants, nurse midwives, nurse practitioners)
  – Is applicable only if both of the criteria below are met:
    • PPT testing in the institution is performed under the same CLIA number as the laboratory
    • Laboratory director is responsible for assessment of competency of providers to perform PPT
  – Contains basic elements on policies/procedures, QC, instrument maintenance, training, competency assessment, results reporting
# Provider Performed Testing

<table>
<thead>
<tr>
<th>Test</th>
<th>PPT</th>
<th>PPM</th>
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<tbody>
<tr>
<td>Amniotic fluid pH</td>
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<tr>
<td>Cervical mucous smears (ferning)</td>
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<td>X</td>
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<tr>
<td>Fecal leukocytes</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Gastric biopsy urease</td>
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<tr>
<td>Nasal smears for eosinophils</td>
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<td>X</td>
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<tr>
<td>Occult blood, fecal &amp; gastric</td>
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<tr>
<td>Pinworm examination</td>
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### Provider Performed Testing

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<thead>
<tr>
<th>Test</th>
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<tbody>
<tr>
<td>Post-coital mucous examination</td>
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<td>X</td>
</tr>
<tr>
<td>KOH prep</td>
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<td>X</td>
</tr>
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<td>Semen analysis, qualitative</td>
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<tr>
<td>Urine sediment microscopy</td>
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<td></td>
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<tr>
<td>Vaginal wet mount microscopy</td>
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</tbody>
</table>
Competency Assessment (GEN and POC)

- **GEN.55500 and POC.06900 (Phase II)**…underlined text is new for 2007
  - Require annual competency assessment of personnel (also, at 6 months after initial training)
  - Elements of assessment:
    1. Test performance including, as applicable, patient ID and prep, specimen collection, handling, processing
    2. Reporting results, including, as applicable, critical results
    3. Review of worksheets, QC records, PT results, maintenance records
    4. Direct observation of instrument maintenance
    5. Assessment by testing previously tested samples, blind testing or PT samples
    6. Evaluation of problem-solving skills
Competency Assessment (GEN and POC)

• Previous text: All applicable elements must be assessed
• New text (2007): It may not be necessary to assess all of the above elements for each individual on an annual basis. The Director should identify and incorporate the elements most pertinent to the testing being performed.
• New in 2007: Specific inclusion of specimen collection and critical results reporting
Controls

• Traditional accreditation and CLIA-88 regulatory requirement:
  – 2 external surrogate sample* controls each day of patient testing
    • 2 levels for quantitative tests
    • Positive and negative for qualitative tests
  – Exceptions for certain tests
    • Coagulation
    • Blood gases
    • Manual tests: ESR, body fluid counts, etc.
    • Bacteriologic media, reagents, stains

*Surrogate sample = a specimen designed to simulate a patient sample for quality control purposes
Current CAP Requirements for External QC in Tests with Built-in Controls

• Criteria for reduction in frequency in external controls
  – These are empirical
  – They apply to all nonwaived tests with built-in controls but leave wide latitude to the laboratory director

• Comprehensive checklist items summarizing the requirements are present in the Autumn 2007 edition of:
  – CHM, POC, IMM and Molecular section of the MIC Checklists (Ph II)
    • CHM.13900, POC.07300, IMM.34120, MIC.63262
New Technology in Controls

• *Built-in* controls (often in single-use devices)
  – Electronic controls
  – Procedural (flow) controls
  – Built-in surrogate sample controls (ex., built-in antigen to react with antibody in the reagent; liquid controls in cartridges)

*Preferable to the word “internal”*
Current CAP Requirements for Nonwaived Tests with Built-in Controls

- Daily controls may be limited to built-in controls only, if and only if all the following criteria are met:
  1. The test system is FDA cleared/approved, not highly complex, not modified by the lab
  2. For quantitative tests, the system includes 2 electronic/procedural/built-in controls run daily
  3. For qualitative tests, the system includes 1* electronic/procedural/built-in control run daily

*Item 3 is new in the Autumn 2007 checklist edition
Current CAP Requirements for Nonwaived Tests with Built-in Controls

(Cont.)

4. The laboratory has performed a validation study to assure the adequacy of limiting daily QC to built-in controls
   • The form of the study is up to the laboratory director with one exception:
     – For tests with built-in liquid controls, specimens should be run daily for at least 20 days comparing external surrogate sample controls to the internal controls. If results are not concordant (based on manufacturer precision data), laboratory director should determine the appropriate action (further studies, continue to run daily external controls, etc)
Current CAP Requirements for Nonwaived Tests with Built-in Controls

(Cont.)

5. External surrogate sample controls are run for each new lot or shipment of test materials
   • This criterion is important to check for problems affecting multiple units incurred during shipping (temperature variation, physical damage, etc)
   • Repetition of the entire original validation study is not required
   • For qualitative tests, best practice is to run a weak positive external control, if available
     – For molecular testing, this control is termed a “sensitivity” control and should be a previously tested patient specimen
Current CAP Requirements for Nonwaived Tests with Built-in Controls

(Cont.)

6. External surrogate sample controls are run at least as frequently as recommended by manufacturer
Current CAP Requirements for External QC in Tests with Built-in Controls

• Tests for Which More Frequent External QC is Required—Every 8 Hours
  – Coagulation
  – Blood gases

• Built-in controls must be run every 8 hours

• Manufacturers generally require every 8-hr internal controls
Other QC Revisions in 2007

• Automated reticulocyte QC (HEM.35100, Phase I)
  – 2 levels of control material per 24 hrs (previously was every 8 hrs)

• Gram stain QC (MIC.21540, Phase II)
  – Gram pos and gram neg controls required weekly and for each new batch of stain
  – (New for 2007) Personnel who perform gram stains infrequently should run a gram-positive and gram-negative control for each day of testing
CAP Patient Safety Goals & Checklists

• “Patient safety” is the public face of quality

• CAP Goal: To position the College as the leader in patient safety and quality of laboratory medicine
Current CAP Patient Safety Goals

• Improve patient and sample ID at time of specimen collection, analysis, and resulting
• Improve verification and communication of life threatening/life altering information
  – Malignancies
  – HIV and other infections
  – Cytogenetic abnormalities
  – Critical values
Current CAP Patient Safety Goals – 2

- Improve identification, communication, and correction of errors
- Improve coordination of laboratory patient safety role within healthcare organizations
Current CAP Patient Safety Goals

- Checklist contains multiple requirements related to patient safety goals
  - Patient identification: GEN.40490
  - Sample identification: GEN.40491
  - Communication of dx of:
    - Malignancy: ANP.12175
    - Infectious disease: GEN.41316
    - Cytogenetic abnormalities: CYG.31931
    - Critical results: GEN.41320
  - Error correction: GEN.20262
  - Coordination with institution: GEN.15354
Current CAP Patient Safety Goals

GEN.20365  Phase II

Does the laboratory address the current CAP Laboratory Patient Safety Goals?

NOTE:…Laboratory processes related to the Patient Safety Goals must be evaluated on an annual basis.

• Note at beginning of GEN:
  Approaches include monitoring activities related to the goals (for example, number of mislabeled specimen containers), with corrective/preventive action as necessary; investigation of mislabeled specimen containers), 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.

• Each goal need not necessarily be monitored at all times…
Current CAP Patient Safety Goals

GEN.41316   Phase I

• **Previous wording:**
  Is there a policy regarding the timely communication, and documentation thereof, of new diagnoses of HIV infection, and other infectious diseases of particular significance?

• **New (2007) wording:**
  Is there a policy regarding the timely communication, and documentation thereof, of diagnoses of infectious diseases of particular significance (e.g., human immunodeficiency virus, tuberculosis, etc.)?
Current CAP Patient Safety Goals

• NOTE: The laboratory should have a policy to ensure that the diagnoses of human immunodeficiency virus infection, and other serious infections (for example, tuberculosis) are communicated to the responsible clinician in a timely manner.

• Addition to Note in 2006:
The intent of this checklist item is NOT to require that these diagnoses be treated as critical results (this decision is up to the laboratory director); rather, the intent is that the laboratory assure that its reporting system is effective.
Critical Results

• CLIA-88 (493CFR1291(g)): The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition.…
  – Key word is “imminently”
Critical Results

GEN.41320    Phase II

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?
Critical Results

• GEN.41320 (Ph II), cont.
  – Note: Critical results should be defined by the laboratory director, in consultation with the clinicians served.
    • Critical results are institution-specific
    • Critical results may be different in different patient populations (renal dialysis patients, oncology patients, inpatients vs outpatients, etc.)

*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 report critical results.*
Critical Results

GEN.41340 Phase I
When critical results are communicated verbally or by phone, is there a policy that laboratory personnel ask for verification “read-back” of the results?

• New text in Note for 2007 underlined:

  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.

  Laboratory personnel should document the read-back.
POC.04600 Phase II

Is there documentation of notification of the physician or other clinical personnel responsible for patient care of results of all critical results?

NOTE: These records must include: date, time, responsible testing individual, person notified and test result(s). The identity of the testing individual and person notified need not be documented when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be documentation of the critical result, date and time in the test report or elsewhere in the medical record.
Patient ID Prior to Collecting Samples

• 2007 Edition
  – GEN.40490 (Ph II), patient identification
    1. 2 identifiers (name and birth date, etc) for both in- and outpatients
    2. (Revised) When possible, ask patient to verbally identify self

• (New) TRM.40235 (Ph II): Patient verbally verifies identity when possible
Patient Safety Goal: Patient and Sample ID

• **New checklist items (2007)**

CYP.03333 Phase II
If the pathologist performs FNA procedures or if laboratory personnel participate in FNA procedures, are patient identifiers placed on the prepared slides and any specimen container at the time of the procedure?

*NOTE: All specimens must be labeled at the time of collection to provide unique identification. Each prepared slide must be labeled separately and any specimen container with collected material (e.g., fluid from aspiration) must also be labeled.*

CYP.03366 Phase I
If the pathologist performs FNA procedures, is there a documented procedure to prevent errors in the identification of the patient, the site and the procedure?
Patient Safety Goal: Patient and Sample ID

  HEM.21575 Phase I
  If the pathologists perform bone marrow aspiration and/or biopsy procedures, is there a documented procedure to verify patient identification, procedure site and the procedure to be performed?

- Reference:
  http://www.jointcommission.org/PatientSafety/UniversalProtocol/
  - Similar new checklist question in HEM, for collection of bone marrow specimens
Checklist question TRM.30550 was added in the 12/29/2004 edition

This checklist question and note and 2 components

1. Monitoring/QI, and
2. Implementation of preventive methods

**TRM.30550  Phase II**

Does the facility have a documented program to ensure that the risk of pre-transfusion sample misidentification is monitored and subjected to continual process improvement?

1. Active monitoring required
2. Suggested methods to reduce pre-transfusion sample misidentification [note]:
   - Mechanical barrier systems
   - Electronic labeling systems
   - Duplicate sampling of patient blood
Does the facility have a documented program to ensure that the risk of pre-transfusion sample misidentification and other causes of mistransfusion are monitored and subjected to continual process improvement?

New Note: The laboratory must actively monitor the key elements of the transfusion process, including, as applicable, donor management, unit production and handling, sample identification and testing, and the transfusion itself including recipient identification.

Changes were:
1. The monitoring system must include not only pre-transfusion sample misidentification, but also other causes of mistransfusion
2. Second component—methods to reduce pre-transfusion misidentification—deleted and moved to new checklist question
Phase I checklist question (new in 2006) **TRM.30575:**

**Does the laboratory have a plan to implement a system to reduce the risk of mistransfusion for non-emergent red cell transfusions?**

- This question is not about monitoring; it is about implementation of a system to reduce risk of mistransfusion. Suggested systems:
  1. Second blood draw to confirm intended recipient blood type
  2. Mechanical barrier system
  3. Electronic identification verification system
  4. Another system that is capable of reducing the risk of mistransfusion

- A second banding identification system does not meet the intent of the checklist item

- The question is Phase I; asks for a plan of implementation of a system

- After a period of time, the question will require such a system and will become Phase II
Transfusion Medicine

• 2007 edition of TRM
  – Revision to TRM.30575:
    • Replacement of text disallowing manual banding ID system with:
      \[\text{The use of a second manual banding system, while currently acceptable, is probably not as effective as the above two options. Other approaches capable of reducing the risk of mistransfusion may be used.}\]
Revisions to Microbiology Checklist

• Special May, 2007 edition—expanded Molecular Microbiology section
  – New checklist items on:
    • Technologist training (MIC.63254, Ph I)
    • Controls – detailed requirements (MIC.CCC01, Ph II in Sept 07 edition, replacing MIC.63258, 63262 in May 07 edition; MIC.63266, Ph II; MIC.63270, Ph II)
    • Procedure manual (MIC.63298, Ph II; MIC.63302, Ph I)
    • Assay validation (MIC.63306, MIC.63310, Ph II) – including requirement that director reviews verification studies and approves tests for clinical use
    • Specimen handling (MIC.63314, 63318, 63322, Ph II)
Revisions to Molecular Micro, cont.

– New checklist items on (cont.):
  • Results reporting (MIC.63326, Ph II; MIC.63330, Ph I)
  • Checking new lots of reagent (MIC.63575, Ph II)
  • Carry-over in nucleic acid amplification (MIC.63800, Ph II)
  • Instrumentation
    – Pipettes, dilutors, etc (MIC.64598, Ph II)
    – Thermocyclers (MIC.64614, Ph I)
    – Fluorescence microscopy (MIC.64630, Ph I)
Molecular Section of Microbiology Checklist

• Introduction

NOTE: When specimens are referred to outside reference laboratories, such laboratories must meet the requirements in GEN.41350 and other applicable requirements in the “Reporting of Results” section of the Laboratory General checklist. (Added in special May 2007 edition of MIC)

GEN.41350 Phase II

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

NOTE: … “Referred specimens” includes any for which intermediate processing is performed at another facility, such as histopathology/cytology preparation or nucleic acid sequencing*

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.

*New text in Autumn 2007 edition
Molecular Section of Microbiology Checklist

This section covers molecular testing for unmodified, FDA-approved molecular methods only. Microbiology laboratories that have modified FDA-approved methods, or that use molecular methods that are not FDA-approved, must also be inspected with the Molecular Pathology checklist. This checklist may also be used by laboratory sections other than microbiology, which perform unmodified, FDA-approved molecular assays.

A database of FDA-approved/cleared tests can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm
HPLC for Identification of Mycobacteria

- New section in Microbiology checklist, Autumn 2007 edition
  - Checklist items on calibration, controls, availability of chromatogram patterns for known strains, carry-over detection, appropriate growth media, validation, assurance of purity of cultures
  - This section is printed only if microbiology lab reports HPLC on its activity menu
Document Control

• Definition (from Dr. Castellani): The process by which the instructions in use can be assured to be current, correct and available.
Document Control

GEN.20375—Does the laboratory have a document control system?

– Changed from Phase I to Phase II in 2006
– Requirement:

The laboratory must have a document management or control system to assure that: 1, all copies of policies and procedures are current; 2, personnel have read the policies/procedures relevant to their job activities; 3, all policies/procedures have been authorized by the laboratory director or designee before implementation; 4, policies and procedures are reviewed at least annually by the laboratory director or designee; 5, discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine).

*Changed from “should” in 2007 Autumn edition

**Designee who authorizes new procedures, or significant changes to procedures, must be qualified as a director (CLIA-88 42CFR493.1251(d)); designee who performs routine annual procedure review need not be qualified as a director
Document Control – GEN.20375

• Requirements
  – Access to electronic procedures when LIS down (paper copies; on CD accessible by other computer, etc)
  – Readily available for inspector in electronic or paper form
  – Quality management records, forms and procedures are subject to document control (GEN.20376, Ph II)

• Recommendation
  – Control log recording status of required elements, and locations of copies and derivatives (card files, charts)

• For electronic procedures, secure electronic signature attesting to approval/review is not required
Water Quality

• Revised checklist section in GEN, in accordance with new CLSI Guideline C3-A4, Preparation and Testing of Reagent Water in the Clinical Laboratory, 2005
  – Significant changes
    • Water no longer classified as Type 1, 2 or 3
    • Now only one type of water is specifically defined: Clinical Laboratory Reagent Water (essentially equivalent to the old Type 1 water)
    • Specifications for CLRW at time of in-house production:
      – Maximum microbial content: 10 CFU/ml
      – Minimum resistivity: 10 megaohm-cm
      – Particulate matter: .22 mu filter
      – Silicate concentration requirement deleted
Water Quality

• Required monitoring for CLRW: resistivity and microbiologic culture

• Monitoring other contaminants is at discretion of laboratory—depends on evidence that testing may be affected
  – Silicates (change from previous edition, in which silicate monitoring was Phase I requirement)
  – pH
  – Endotoxin/pyrogens
  – Total organic carbon
Water Quality

• “Sterile (pharmaceutical) water” is not equivalent to CLRW

• Other types of water – defined by laboratory or manufacturer
  – Special reagent water
    • Defined individually by laboratory, for a specific use requiring water different from CLRW
  – Instrument feed water
    • Specified by manufacturer for a specific test
  – Commercially bottle purified water
    • Suitable for specific tests

• For commercial test systems, laboratory must use water specified by manufacturer
Proficiency Testing

• For 2007
  – Some checklist items have been reformatted to improve clarity
  – Some redundant items have been deleted
  – Two new checklist items
Proficiency Testing
GEN.10000, 10500 Ph II

• Participation required for all analytes designated by CAP
  – Refer to list on Web site
    • Click on Accreditation/Laboratory Improvement, then Proficiency Testing Performance, then 2007 PT Enrollment Guide

• For non-required analytes (2x/year):
  – PT, or
  – Alternate performance assessment

• For FISH tests, laboratory may perform alternative assessment by method and specimen type, rather than for each probe or abnormality (ie, one assessment program for all FISH studies performed on cell suspensions, etc)…CYG.10550 and MOL.10160
New Checklist Item in PT Sections

CHM.05000  Phase I
Does the laboratory’s current CAP Activity Menu accurately reflect the testing performed?

*NOTE: An accurate Activity Menu is required to properly assess a laboratory’s compliance with proficiency testing requirements. The accuracy of the Activity Menu can be assessed by inquiry of responsible individuals, and by examination of the laboratory’s test requisition(s), computer order screens, procedure manuals, or patient reports. All tests performed by the laboratory should be listed on the Activity Menu, and vice versa.*

*If tests are identified that are not included on the laboratory’s test menu, the inspector should contact the CAP (800-323-4040) for instructions. (Additional custom checklist sections may need to be sent to inspector)*
FLO.18385    Phase I
For laboratories that perform only interpretations of flow immunophenotyping data for leukemias and lymphomas, does the laboratory participate in a peer education program in interpretive flow cytometry of hematolymphoid neoplasia?

NOTE: This checklist item applies to laboratories which do not perform staining and acquisition of flow cytometry data, but which receive [1] list mode files and/or [2] representative dot plots from an outside laboratory for interpretation.

FLO.23706    Phase II
Are grated dot plots and histograms retained for at least 10 years?

REFERENCE: CAP Policy PP, Retention of Laboratory Records and Materials
“Technical Consultant” Section Added to TLC in 2006 Edition

- A position defined by CLIA-88 for laboratories performing moderately complex tests
- May be the same individual as the director, if director is qualified; director of high-complexity laboratory is so qualified
- TC not included in LAP requirements in the past, b/c LAP required all directors to meet CLIA requirements for high complexity laboratories…UNTIL 2006 edition
  - 2006 LAP instituted less stringent director requirement for laboratories performing moderately complex tests (and test volume <=500,000 annually)
    - MD/DO/DPM with 1 yr experience supervising nonwaived testing, or 20 hrs CME in laboratory medicine
    - Doctoral scientist with 1 yr experience supervising nonwaived testing
    - TC required for laboratories that perform moderately complex tests that are directed by individuals qualified as (a) or (b) above
Technical Consultant

- Must be qualified as director of high complexity laboratory (TLC.12550, Ph II)
- Lab must have agreement defining responsibilities of TC (TLC.12650, II) (493CFR1413)
  - Oversight of technical and scientific aspects of laboratory
    - Selection of test methods
    - Verification of method performance specifications
    - Participation in PT
    - QC program
    - Resolving technical problems
    - Competency of personnel
  - Need not be on site at all times but must be available by telephone/electronic means
Technical Consultant

• Activities of TC must be documented (TLC.12700, Ph II)
• TC responsibilities overlap with some director responsibilities
• CLIA also requires a “clinical consultant” in moderately complex laboratories, but CAP has no such requirement
  – CAP does not permit masters of bachelors level individuals to direct these laboratories; thus laboratory director can serve as clinical consultant
Questions
Technical Assistance

http://www.cap.org

Email: accred@cap.org

800-323-4040, ext. 6065