LABORATORY ACCREDITATION MANUAL

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INTRODUCTION

Overview of Accreditation Programs

The College of American Pathologists (CAP) has established and directs three separate accreditation programs, all created with the primary objective of improving the quality of clinical laboratory services. All employ voluntary participation, professional peer review, education, and compliance with established performance standards. Since their creation, these programs have become widely acknowledged for excellence. In all, the College accredits over 6,600 laboratories.

The Laboratory Accreditation Program (LAP) was established in 1961. In 1995, it received approval as an accrediting organization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) by the Centers for Medicare and Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services. The Forensic Drug Testing (FDT) accreditation program was established in 1988. The Reproductive Laboratory Program (RLAP), directed jointly with the American Society for Reproductive Medicine (ASRM), was established in 1993.

The mission statement of the CAP Laboratory Accreditation Program is:

> *"The CAP Laboratory Accreditation Program improves patient safety by advancing the quality of pathology and laboratory services through education and standard setting, and ensuring laboratories meet or exceed regulatory requirements."*

The vision of the College is to be the world's leader and innovator in Laboratory Accreditation.

The accreditation programs examine pre-analytical, analytical, and post-analytical aspects of quality management (QM) in the laboratory. These include the performance and monitoring of general quality control (QC), test methodologies and specifications, reagents, controls and media, equipment, specimen handling, test reporting and internal performance assessment, and external proficiency testing. In addition, personnel requirements, safety, document management, and other administrative practices are included in the inspection process. Laboratories that meet accreditation requirements distinguish themselves as quality laboratories.

Accreditation Hierarchy

The Council on Accreditation (CoA) sets the strategic direction for the CAP Laboratory Accreditation Program consistent with the College's vision and monitors its overall effectiveness in ensuring that participating laboratories meet regulatory and CAP requirements. The CoA also provides oversight to the Commission on Laboratory Accreditation (CLA), a group of qualified pathologists appointed to advance the Laboratory Accreditation Program to be the premier program for the inspection and accreditation of medical laboratories; to administer the programs through the principles of peer review and education toward the goal of laboratory improvement in order that quality laboratory services are provided to patients and clients; to ensure that the programs continue to meet the scientific, service, and regulatory needs of participants; and to enhance the recognition of the pathologist as a physician in clinical decision-making and consultation through the role of laboratory director.

The CLA oversees and coordinates the activities of the five CLA committees in the development, maintenance, and implementation of (i) accreditation checklists and standards, (ii) inspection processes,

(iii) inter-inspection assessment tools, (iv) complaint investigations, and (v) program education; the CLA also ensures that committee priorities and activities are aligned with the overall goals, strategies, and tactics supporting the Laboratory Accreditation. The CLA uses the expertise of numerous CAP scientific resource committees to keep the programs and their requirements current.

The Accreditation Committee is another arm of the CoA responsible for ensuring objectivity and consistency in CAP accreditation decision-making by centralizing the decision-making criteria and processes. The Accreditation Committee makes investigation and accreditation decisions in those cases requiring committee action based on approved policy (i.e., more challenging and immediate jeopardy cases that may require a non-routine inspection, suspension, probation, or conditional accreditation decisions).

Commissioners

Many of the members of the CLA also serve as Regional Commissioners. Each Regional Commissioner is responsible for all accreditation activities of a specified group of laboratories. This includes the timely assignment of inspectors, review of inspection findings, and resolution of issues that may arise over accreditation decisions. Following the on-site inspection, the Regional Commissioner, in conjunction with CAP technical staff, reviews the findings and the laboratory's corrective action, and conducts any follow-up necessary to reach an accreditation decision.

Deputy, State, and Division Commissioners assist the Regional Commissioners. State and Division Commissioners are responsible for identifying and assigning inspectors for their geographic regions. They must make sure that inspections are conducted on a timely basis and in accordance with CLA policy.

Inspectors and CAP Staff

The inspectors who conduct the on-site laboratory inspections are the lifeblood of the program. Typically, the inspection team leader is a board-certified pathologist who has received training and has participated in several inspections as a team member. Inspection team members are other pathologists, doctoral scientists, supervisory-level medical technologists, pathology residents and fellows, and other individuals who have expertise in the area of the laboratory that they are to inspect.

The Laboratory Accreditation staff at the CAP headquarters in Northfield, Illinois, is composed of technical and administrative personnel who carry out the policies and procedures of the CLA, and are responsible for the management and operation of the program.

Accreditation Documents

In addition to this manual, three other documents are fundamental to the inspection process: The *Standards for Laboratory Accreditation,* the checklists, and the Inspector's Summation Report (ISR). Through peer review, the inspector uses the checklists to determine if the laboratory meets the requirements set out in the *Standards*. The inspector collects information and records it on the ISR, and this information is the basis for the Regional Commissioner's accreditation decision. In addition to verifying that regulatory requirements are being met, the inspection entails sharing information and ideas between the individuals comprising the inspection team and the laboratory being inspected. This sharing of information results in ideas for laboratory improvement for both the laboratory being inspected and the

members of the inspection team, who often take a new idea or process back with them to their laboratories.

Communication of Changes to the Laboratory Accreditation Program

One method of communicating changes in Accreditation Program policies and procedures to participants is the Laboratory Accreditation News section of *CAP TODAY*. Published three times per year, Laboratory Accreditation News can also be downloaded from the CAP Web site. Refer to Appendix E for information about subscribing or renewing.

Inspection Learning Objectives

Having completed an inspection, the inspector should be able to:

1. Use the *Standards for Laboratory Accreditation* and the Inspection Checklists to evaluate a laboratory.
2. Identify new methods, technology, and/or approaches in laboratory medicine.
3. Recognize current management issues and solutions.

Standards for Laboratory Accreditation

The *Standards* are the basis for the accreditation decision. Each of the three accreditation programs has its own *Standards for Laboratory Accreditation*. The CAP Board of Governors approves the *Standards*, which have evolved through years of study and continuous review by the Commission on Laboratory Accreditation. The inspector must be familiar with each *Standard* and its interpretation. A copy of the *Standards* is included with each inspection packet, and must be reviewed before the inspection of the laboratory. The inspection team leader is considered the on-site authority for the interpretation of the *Standards.*

Standard I relates to the qualifications, responsibilities, and role of the **laboratory director**. It discusses which responsibilities may be delegated and the role of a consulting pathologist.

Standard II concerns the **physical facilities and safety of the laboratory**, including space, instrumentation, furnishings, communication systems, supplies, ventilation, piped gases and water, public utilities and security.

Standard III encompasses **quality control and performance improvement**. This includes discussions of quality control, proficiency testing, instrument maintenance, quality management, and performance improvement requirements.

Standard IV includes the **inspection requirements** of the program. On-site inspection by an external team and interim self-inspection are the cornerstones of the inspection requirement. Participating laboratories also provide an inspection team when requested.

Checklists

Each checklist is a detailed list of requirements that the inspector uses to determine if the laboratory meets the *Standards*. They also serve as instruments to guide the conduct of the inspection. The checklists are

revised periodically and include approximately 3,000 questions. Similar checklist questions may appear in multiple discipline-specific checklists.

The checklists are organized by specific laboratory disciplines and/or important management operations as follows:

- Laboratory General
- Anatomic Pathology
- Chemistry and Toxicology
- Cytogenetics
- Cytopathology
- Flow Cytometry
- Hematology and Coagulation
- Histocompatibility
- Immunology
- Limited Service Laboratory
- Microbiology
- Molecular Pathology
- Point-of-Care Testing
- Team Leader Assessment of Director & Quality
- Transfusion Medicine
- Urinalysis
- Forensic Drug Testing
- Reproductive Laboratory

Checklists are automatically mailed to accreditation program participants approximately nine months prior to the inspection anniversary date and again at accreditation mid-cycle during the self-evaluation year.

To receive the checklists:

- Call 800-323-4040, extension 6055, or 847-832-7000, extension 6055 for a copy in printed format or on CD.
- Download an electronic copy from the CAP Web site at www.cap.org.

During the inspection, the checklist questions are used to evaluate whether or not a laboratory meets the *Standards*. Each question is uniquely numbered, worded, and designed to produce: a "Yes" response, which means that the laboratory is in compliance with the item; a "No" response, which means the laboratory does not comply; or N/A, which means that the question does not apply in this situation.

Laboratories will be inspected using the checklist version sent to them at the time of application/reapplication, even when a new version has been released into the field since that time. The inspection team is sent, and must utilize, the same version sent to the laboratory for its on-site inspection. It is likely that the checklist version sent for use in the self-evaluation will be different from the version used for the previous or next on-site inspections.

Visit the CAP Web site Virtual Library of Audioconferences to hear the most recent "Checklists Update" audioconference. This is an annual topic of LAP audioconferences.

Determining Checklist Changes: a listing of new, revised, and deleted question numbers follows the table of contents of each checklist. A new, revised, or deleted question number will remain on the list for 18 months.

New checklist questions are indicated by the flag "NEW" and the date of the edition in which the question first appeared. Significantly revised questions are marked with a "REVISED" flag and the date of the edition in which the revision first occurred. The flags are removed three editions after the checklist in which the flag is set.

As the checklists are revised, each will exist in three versions at the CAP Web site:
1. Current version
2. Previous versions
3. "Changes" versions: contains ONLY what has been changed, added, or deleted.

These versions will remain at the Web site until they are no longer used in the field.

Phase I and Phase II Deficiencies

Each checklist question bears a designation of Phase I or Phase II. Deficiencies to **Phase I** questions do not seriously affect the quality of patient care or significantly endanger the welfare of a laboratory worker. If a laboratory is cited with a Phase I deficiency, correction and a written response to the CAP are required, but supportive documentation of deficiency correction is not required. A Phase I requirement may also be a new checklist question, which in subsequent checklist editions may be changed to Phase II.

Deficiencies to **Phase II** questions may seriously affect the quality of patient care or the health and safety of hospital or laboratory personnel. All Phase II deficiencies must be corrected before accreditation is granted by the CLA. Correction requires both a plan of action and supporting documentation that the plan has been implemented.

To anticipate and prepare for upcoming changes to checklist requirements, laboratories are encouraged to download and review the most recent edition of each checklist available via the CAP Web site at www.cap.org. The Web site "checklist with commentary" format includes not only checklist questions and explanatory commentary, but also references that may be helpful to the laboratory in determining corrective action. Commentary providing information that assists with the interpretation or understanding of the checklist requirement is being systematically moved from the commentary area into the *NOTE* area of the checklist question. Information in the *NOTE* is integral to the checklist question; accredited laboratories must comply with requirements in the *NOTE*, just as in the checklist question itself.

COMMISSION PHILOSOPHIES

Peer Review

Purpose: Improve laboratory performance through objective evaluation and constructive criticism.

The inspector can enhance the spirit of peer review and the educational benefit of the inspection process by adhering to the following:

- As representatives of the accreditation program and the CAP, inspectors must strive for an objective and fair review. There is often more than one way to comply with a requirement.
- The inspection team leader should be a peer of the laboratory director and serve as a guest consultant to the laboratory.
- Deficiencies should be presented factually. Provide recommendations for improvement, if possible.
- A negative, unduly critical, or punitive attitude should be avoided.
- Deficiencies cited by the inspection team may be challenged. If resolution of a disagreement between laboratory personnel and an inspector cannot be achieved before or during the summation conference, the director may challenge the deficiency during the post-inspection process. Refer to the section "Post-inspection Phase: Challenging a Deficiency" in this manual (see page 87).

Thoroughness

CAP inspections are approved by the Centers for Medicaid and Medicare Services (CMS) and must meet all regulatory requirements. Additionally, participating laboratories expect a thorough, detailed, and fair inspection. All pertinent items in the customized checklist should be inspected. Since laboratories must be inspection-ready at all times, in addition to providing quality patient care, they appreciate validation of the work they do and deserve a comprehensive inspection. Minor deficiencies should not be overlooked.

Judgment

The Commission relies upon the inspector's judgment more than any other attribute in the assessment of a laboratory. This attribute is, however, the most difficult to standardize. There will be occasions when a conscientious inspector will have difficulty deciding whether a checklist item should be answered "Yes" or "No" or "N/A." Many of these decisions involve assessment of partial compliance with the checklist requirement. Therefore, the inspector must describe the deficiency as completely as possible in the Inspector's Summation Report. This description should include details of the sampling that was performed to assess compliance with the requirement. For example, a description may include, "In the review of xx number of records for a specific expected result, the laboratory was found to be out-of-compliance with xx records." With this detailed information, LAP can better assess the corrective action that the laboratory proposes.

Disputes

To help resolve questionable citations, the Laboratory Accreditation technical staff may assist an inspector by telephone during the inspection. If a laboratory wishes to challenge a particular citation, it must state its disagreement in the deficiency response and provide documentation to demonstrate how the lab was in compliance before it was inspected. The Regional Commissioner will review disputed items and determine if the deficiency can be removed from the record.

Harassment

Employees of laboratories inspected by the CAP are entitled to a workplace environment that is free from sexual or other unlawful harassment. Prohibited sexual harassment includes any comments, gestures, innuendo, or physical contact of a sexual nature that create an intimidating, offensive, or hostile environment. Also prohibited are behaviors that harass an employee based on race, gender, disability, age, religion, national origin, or other legally protected category.

Inspectors on a CAP team, whether the team leader or a team member, must never display conduct that can reasonably be construed as harassment. Team leaders must ensure that the behavior of team members is consistent with this position; they must intervene actively if inappropriate conduct is observed.

Inappropriate conduct on the part of team leaders or team members should be reported to the Director of the Laboratory Accreditation Program. The CAP does not tolerate harassment. In cases of documented harassment, the CAP will take appropriate action.

Solicitation

Inspectors should not solicit in any way either the institution or the laboratory for any purpose. They must never display conduct that can be reasonably construed as a solicitation. Inspectors should not request any information from the institution or laboratory regarding fees or other business-related matters. The inspector should not request any information regarding the director's contractual relationship with the institution's administration. However, when the medical director is there less than full time, it is appropriate to ask about contractual agreements indirectly to ensure that the needs of the hospital are met.

Confidentiality

All inspection findings are confidential. They should not be discussed in any context other than the inspection itself. Moreover, they should not be disclosed to anyone not associated with the accreditation process unless appropriate prior documented consent has been obtained.

Confidentiality – HIPAA Privacy Rule

Any U.S.-sited laboratory inspected by the CAP or by any other accrediting agency is required to have an agreement between itself and the accrediting agency protecting the privacy and security of patient health information. The College has developed for its accredited laboratories a standardized model agreement to be used to meet the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirement. The model business associate agreement is posted at the CAP Web site.

The CAP further protects the CAP-accredited laboratory by informing its inspectors and any other personnel who may have access to protected health information of their obligation to keep this information confidential and to use such information only within the context of the inspection itself. The Inspector's Summation Report includes an agreement from each inspector indicating that he or she will treat protected health information confidentially.

Inspector Liability

The CAP Bylaws include a provision that indemnifies volunteers, including inspectors, against liability and expenses, including attorney fees, incurred in connection with any legal action in which the individual is made a defendant by reason of the individual's good faith efforts on behalf of the College. Inspectors approached in this regard by a laboratory, patient, or an attorney regarding inspection activities should contact the College immediately to invoke this provision. Inspectors should not discuss any inspection findings with anyone outside the inspected laboratory or the College.

Conflict of Interest

Accreditation must be carried out in an impartial and objective manner, uninfluenced by any personal, financial, or professional interest of any individual acting on behalf of the CAP Laboratory Accreditation Program. Inspectors must not be engaged in close personal, family, business, or professional relationships with any personnel in a laboratory that the inspector inspects. An inspector must not solicit or accept gifts of any type, including personal gifts, products, services, or entertainment. Neither shall an inspector discuss, solicit, accept, or have an employment or consulting arrangement, referral of business, or other business opportunity with the laboratory that the inspector inspects.

However, the CLA believes that an inspection performed by a team from a laboratory or institution that competes with the subject laboratory or institution does not represent a conflict of interest. The inspection team does not make the accreditation decision, and the subject laboratory may challenge any deficiency citation. Further, the CLA believes that team leaders and inspectors will conduct inspections objectively and professionally, regardless of whether they are in competition with the subject institution. Prior to unannounced inspections, the team leaders are required to sign a statement attesting to the absence of conflict of interest.

For all initial inspections and international laboratories, as well as inspections of laboratories participating in the CAP Reproductive Laboratory Accreditation (RLAP) or Forensic Drug Testing (FDT) accreditation program, the inspected laboratory may discuss the specifics of a perceived conflict of interest with LAP staff or the State and/or Regional Commissioner before the inspection. The State or Regional Commissioner has discretion to recommend reassignment if there appears to be a valid conflict of interest. For unannounced inspections, any laboratory can discuss the specifics of a perceived conflict of interest with the State and/or Regional Commissioner after the inspection.

APPLYING TO THE CAP LABORATORY ACCREDITATION PROGRAM

Proficiency Testing Prerequisite

- Laboratories must participate in a CAP-accepted proficiency testing (PT) program for each patient-reportable analyte, when PT enrollment is required (refer to the PT Enrollment Guide at the CAP Web site).
- Each separately accredited laboratory must be enrolled in an accepted PT program under its own CAP number.

Application

A laboratory that would like to become accredited by CAP must submit an application request form along with a non-refundable deposit. The deposit is applied toward the first year's accreditation fee. Once the request has been processed, application materials will be sent to the laboratory. The application materials are organized into a binder that is divided into four sections. The first section will have all the necessary forms for the formal application. The other three parts of the binder include *The Standards for Laboratory Accreditation,* the *CAP Laboratory Accreditation Manual,* and Inspection Checklists.

A new applicant to the accreditation program has up to six months to complete and return the application materials. If the laboratory chooses to have its initial inspection coordinated with an existing CAP-accredited laboratory, a due date by which the application materials must be returned to the CAP office will be assigned accordingly.

Accreditation is matched one-for-one with CLIA certificates. **Each laboratory within an institution that operates under a separate CLIA license must also be accredited separately by CAP.** Laboratories operating under separate CLIA certificates must submit separate deposits and application request forms.

The *Standards for Laboratory Accreditation,* the *CAP Laboratory Accreditation Manual,* and the Inspection Checklists are available for review at the CAP Web site (www.cap.org) before applying to the program. If you do not have access to the Internet, you may call the Laboratory Accreditation Program at 800-323-4040, extension 6055, or 847-832-7000, extension 6055, to request these documents.

PRE-INSPECTION PHASE: PREPARATION OF APPLICATION MATERIALS

Application Forms and Supplemental Materials

Before the first on-site inspection, each laboratory must complete the following application materials:

- Application forms. These address general laboratory information, including demographics, personnel, contacts, licensure and certification, affiliated laboratories, and conditions of accreditation.
- Laboratory Section pages for each section of the laboratory. The following information must be supplied: Section Name, Responsible Personnel, Technical and Non-Technical FTEs, and an estimated annual test volume. (See Appendix B: Guidance in Determining Test Volume on page 100.) For each Laboratory Section, the laboratory should complete a Master Activity Menu that includes all of the activities performed in that section of the laboratory. These pages may be copied if testing is done in more than one section. Also attached to the section page should be a list of all the instruments and equipment used in that section.
- Personnel Qualification Forms for all laboratory directors, pathologists, administrative managers, supervisors, and the contact persons for Quality Assurance, Proficiency Testing, and receipt of the Application.
- The Commission on Laboratory Accreditation expects that the laboratory will have reviewed all applicable checklist requirements in order to ensure that it meets the *Standards* by the date the application materials are returned to the CAP.
- Supplemental materials, as follows: the Medical Director's curriculum vitae (please remove the Social Security number); for newly appointed Medical Directors, a completed Laboratory Director Questionnaire and Terms of Accreditation form must be submitted; an Organizational Chart including both names and titles; a copy of the laboratory's current CLIA certificate and state licensure certificate; completed FDA Blood Registration Form 2830; a list of POCT test sites; a floor plan of the laboratory; travel and lodging information forms; and the most recent inspection report from the laboratory's former accreditor or state agency, if applicable. For an initial accreditation, include a test catalog.

  Note: Florida laboratories will receive a blank **Clinical Laboratory Personnel Roster** form. The laboratory must complete a roster for each laboratory section, including any non-laboratory-based employees performing Point-of-Care-Testing classified by CMS as moderate or high complexity. The Personnel Roster may be photocopied if more than one page is needed. The completed Personnel Roster must be signed by the preparer and, along with a copy of each employee's State of Florida License, must be returned with the application/reapplication packet.

  Note: Laboratories applying for the Forensic Drug Testing (FDT) Accreditation Program must also submit the following "litigation packet" information:

  - A copy of the laboratory's overall quality control procedure with the specific control materials used for each test (content, concentration).

- A copy of the laboratory's overall chain-of-custody (COC) procedure with a flow chart illustrating the various steps used by the laboratory to ensure specimen integrity from the initial receipt of a specimen to its final disposition.
- A recent (past 30 days) example of a positive THC-COOH data pack in a litigation format. This should include:
  - Standard operating procedure (SOP) for the screening procedure
  - Screening data for the specimens, calibrator(s), and controls
  - Evidence of review of the screening batch
  - SOP for the confirmation procedure
  - Chromatographic data for the specimens, calibrator(s), and controls
  - Determination of quantitation values
  - Determination of ion ratios
  - Evidence of review
  - Copy of the final report (identity of person tested should be blocked out)
  - Copies of specimen and aliquot internal COC

Laboratory Disciplines

All disciplines (see Appendix H: Glossary of Terms) practiced by the laboratory (as defined by the CLIA number) **must be listed in the application, and all disciplines will be inspected**. **The College does not accredit portions of laboratories**.

CAP disciplines/subdisciplines and CMS specialties/subspecialties (when appropriate) will be determined by the selection of activities from the Master Activity Menu. The accreditation letter lists only those disciplines that are reviewed at the time of the on-site inspection. Laboratories that add disciplines after the inspection must notify the College in writing; in some cases, additional inspections may be required. (See the "Non-Routine Inspections" section of this manual on page 95.)

Activity Menu

The laboratory provides information about its scope of testing and lists all reportable assays in the Activity Menu. The information provided is critical, as it will be used to customize checklists, to determine disciplines for which accreditation is granted, to verify proficiency testing enrollment, and to determine the laboratory's annual fee. Accuracy in completing this document is essential.

Reapplication Forms

Laboratories previously accredited by the CAP are provided reapplication forms that are pre-populated with the laboratory's data. The laboratory must verify and update this by supplying missing or new data. All requested supplemental information must be supplied at the time of reapplication.

AABB Coordinated Inspection

Laboratories wanting a CAP/AABB coordinated inspection of their transfusion medicine service must indicate that request on the LAP application/reapplication form. Additionally, these laboratories must notify the AABB (formerly known as the American Association of Blood Banks) national office at 301-907-6977 as early as possible in the application/reapplication process to allow sufficient time for

administrative processing. Please refer to the section in this manual "Preparing for the Inspection" on page 19 for further information on AABB coordination.

Inspection Checklists

- CAP staff determines checklist usage from the activity menu completed for each laboratory section. Depending on the organization of the laboratory, more than one checklist may apply to any one laboratory section. Supervisors should prepare for inspection using the appropriate discipline-specific checklist(s). Similarly, the laboratory director should review the Team Leader Assessment of Director & Quality Checklist, which evaluates the qualifications of the laboratory director in implementing the *Standards* of the Laboratory Accreditation Program, as well as the overall effectiveness of the laboratory's quality management system.
- The checklists used for inspection are customized based on the laboratory's activity menu. Subdiscipline sections and other significant groups of questions not pertinent to the testing performed in the laboratory will not be included. Customized checklists greatly reduce the number of non-applicable checklist questions.
- A complete set of the current version of CAP inspection checklists is included with a laboratory's initial application packet, whereas customized checklists are sent in a reapplication packet. **The version sent with the application/reapplication packet is the one with which the laboratory will be inspected, regardless of whether another version is released between the time of application/reapplication and the actual inspection**. After processing the application/reapplication, the CAP will send the final customized checklists back to the laboratory, and the inspection team is sent the same version. The checklists may be copied for your use, if needed.
- Duplicate discipline-specific checklists are required in instances where there is more than one laboratory section performing testing within the same discipline, and under the operation of different supervisors, (i.e., a separate blood gas laboratory with a different medical or technical supervisor). The appropriate quantity of each checklist will be provided to the inspector.
- **Checklists should not be returned to the CAP office.** See Appendix A for a detailed explanation of checklist usage.

Returning the Application

Return completed application forms and supplementary material to:

LABORATORY ACCREDITATION PROGRAM
COLLEGE OF AMERICAN PATHOLOGISTS
325 WAUKEGAN ROAD
NORTHFIELD, ILLINOIS 60093-2750

PREPARING FOR THE INSPECTION

Training the Inspection Team Leader and Team Members

The CAP has strengthened the qualification requirements for inspectors to include mandatory completion of CAP-prescribed training. Training promotes a consistent understanding of program standards and ensures a uniform application of techniques to achieve a more consistent and effective inspection. Training is mandatory for all team leaders and team members. CAP began to monitor the training of team leaders assigned after 1 July 2006, and will begin to monitor the training of team members at a later date. Until that time, team leaders are responsible for ensuring their team members are trained prior to conducting an inspection.

A variety of specially designed training options is available for Team Leaders and Team Members. Since each option covers the same concepts and strategies, only one is needed to fulfill the training requirement. Each option offers CME/CE credit for participants.

To enroll in any LAP training program, access the CAP Web site at www.cap.org, click on the Education Programs tab, and then choose Laboratory Accreditation Program Education Activities.

Team Leader Training Options
Option One: Comprehensive Online Team Leader Self-Study. This option allows for completion of team leader training entirely online through the Internet. It is available 24 hours a day, seven days a week.

Option Two: Live Inspector Training Seminar. The Inspector Training Seminar is a one-day, intensive, live program. It provides the opportunity to meet and work with other team leaders and team members, as well as interact with regional and state CAP commissioners in a classroom setting.

Option Three: Live Team Leader Workshop/Team Leader Online Practice. This option is a combination of live and online training, beginning with a two- to three-hour live Team Leader Workshop followed by the Team Leader Online Practice course.

Team Member Training Options
Option One: Comprehensive Online Team Member Self-Study. This option allows for completion of team member training entirely online through the Internet. It is available 24 hours a day, seven days a week.

Option Two: Live Inspector Training Seminar. The Inspector Training Seminar is a one-day, intensive, live program. It provides the opportunity to meet and work with other team leaders and team members, as well as interact with regional and state CAP commissioners in a classroom setting.

Additional Continuing Education Resources

LAP Audioconferences: One-hour LAP audioconferences can be accessed directly in your laboratory each year at no cost to you. The entire team can effectively learn about key topics that are of interest to both inspectors and laboratories preparing to be inspected. The laboratory will need to have a speakerphone and to identify a site coordinator. There is no limit to the number who may attend from your laboratory. A minimum of one hour of CME/CE credit/hour is offered per session to each attendee. To register for an LAP audioconference, access the CAP Web site at www.cap.org, click on the Education Programs tab, and then choose Laboratory Accreditation Program Education Activities.

Virtual Library of Audioconferences: Each audioconference is available at the CAP Web site approximately three weeks after the live presentation, including both audio files and handouts. Topics range from inspection basics to "how to inspect" the various laboratory sections and are available 24 hours a day for download. This library is beneficial both to inspectors and to laboratory professionals preparing for their inspection. A sample of available topics includes:

General Topics

- Analytic Requirements
- Calibration/Calibration Verification
- Checklists Update
- Deficiency Case Studies
- Inspecting Personnel (qualifications, evaluation, and competency)
- Inspecting the Laboratory Computer System
- Laboratory Safety
- Patient Safety Goals
- Pre-/Post-analytic Requirements
- Quality Improvement
- Quality Management Plan
- Regulatory Aspects of Accreditation
- Summation Conference
- Systems
- Systems Laboratory Option Update
- Unannounced Inspections and Inspection Day Tips

Discipline-specific Topics

- Cytogenetics
- Inspecting Hematology
- Inspecting Point-of-Care-Testing
- Inspecting the Blood Gas Laboratory
- Inspecting the Cytogenetics Laboratory
- Inspecting Cytopathology
- Inspecting the Flow Cytometry Laboratory
- Inspecting the Histocompatibility Laboratory
- Inspecting the Microbiology Laboratory
- Inspecting the Reproductive Laboratory
- Inspecting the Toxicology Laboratory
- Inspecting the Transfusion Medicine Laboratory

- Is Your Inspection Team Prepared for a Cytology Inspection?
- Microbiology
- Molecular Pathology
- Point-of-Care Testing
- POCT and CAP Accreditation
- Surgical Pathology
- Transfusion Medicine

Team Leader Topics
- Team Leader Essentials
- Using the Team Leader Checklist

Inspector Topics
- Mastering the Process: Helpful Hints for Inspectors

Laboratory Inspection Preparedness Training Topics
- Preparing Inspection Documentation
- Reviewing Laboratory Procedures and Records (policies, PT, QC, maintenance, etc.)
- Solutions for Common Deficiencies
- What to Do with Proficiency Testing Failures
- Your Quality Improvement Plan

Laboratory Inspection Preparedness Training

Laboratories new to the accreditation program and laboratory staff newly responsible for ensuring compliance with checklist requirements may access relevant information in the LAP Virtual Library of Audioconferences. Specific topics are listed in the preceding section. Additionally, the majority of the audioconference topics would also be of value, particularly the discipline-specific audioconferences. These often include what the inspector will look for, and what practices, procedures, and documentation constitute compliance.

Inspection Team Leader Assignment

The inspector assignment process has been improved to maximize the inspection experience. The process matches team leaders to a single prospective assignment after screening against multiple criteria, including completion of training, known conflicts of interest, geographic distance, and size and complexity of the respective laboratory. Assignments will be screened by the CAP LAP state commissioners, and the notification of assignment will arrive by mail.

This improvement to the accreditation program is designed to create better matches between inspection teams and the laboratories they inspect. It will help ensure that each inspection is carried out by an appropriate team, and that the inspection team has the opportunity to inspect a laboratory most like its own.

For unannounced inspections, neither the College nor the team leader will communicate to the laboratory the date of the inspection, the name of the team leader, or the composition of the inspection team.

Refer to Appendix C for Unannounced Inspection Tips for the Laboratory and the Inspectors (see page 101).

Team Leader Qualifications

Team leaders should be:

- A peer of the laboratory director with similar status, type of practice, and hospital or laboratory size.
- Preferably a board-certified pathologist***** and a CAP Fellow.
- Affiliated currently or recently with a CAP-accredited laboratory.
- Trained in the inspection process and team leader responsibilities.
- Not engaged in a close personal, family, business, or professional relationship with any personnel in a laboratory that he/she will inspect.

***** A non-pathologist inspector may serve as the team leader for a laboratory that is typically not directed by a pathologist (for instance, a cytogenetics laboratory) so long as the inspector is a peer of the laboratory director. For a pathologist-directed laboratory, however, a non-pathologist inspector may serve as the team leader only with the prior agreement of the laboratory director. A pathologist board certified in anatomic pathology must inspect the anatomic pathology section, except in the case of a small laboratory doing only specimen accessioning and/or frozen sections. In this situation, the laboratory may be inspected by a CAP Staff Inspector. A CAP Staff Inspector is a staff medical technologist and performs inspections for certain limited service laboratories. The Staff Inspector Assignment Specialist at the CAP office makes these assignments. Refer to "Staff-inspected Laboratories" (see page 78).

Inspector's Inspection Packet

The Inspector's Inspection Packet is sent to the inspection team leader from the CAP office and includes the following materials:

- *Standards for Laboratory Accreditation*
- *Laboratory Accreditation Manual*
- Team Leader Inspection Planner (see Appendix J)
- Team Member Inspection Planner (see Appendix K)
- Accreditation Unit (AU) materials, including:
  1. Variant Proficiency Testing Performance by Laboratory Report
  2. Laboratory Demographic Information
  3. Inspector's Summation Report (ISR) forms
  4. Previous ISR
  5. Lab-specific Activity Menu (list of tests and testing modalities)
  6. Instrument List
  7. Organization Chart and Floor Plan
  8. Laboratory Director's Curriculum Vitae
  9. Checklist Selection Report (list of checklists used for each lab section)
  10. Customized Checklists (customized based on the laboratory's activity menu; the cover indicates the name of the laboratory section in which each checklist should be used)
  11. Travel and Lodging Information

12. Black out dates, along with days and hours of laboratory operation

- List(s) of qualified Specialty Inspectors, applicable to Cytogenetics, Flow Cytometry, Histocompatibility, and Molecular Pathology
- CD-ROM containing checklists, inspection documents, and forms
- Name tags for the team (every team member should wear a name tag while in the host facility)
- Team Leader Evaluation
- Team Member Evaluation
- Inspection Team Member Form
- CME/CE Certificate Request Form
- Claim for Inspection Reimbursement
- Prepaid mailer envelope to return the packet to the CAP after the inspection is complete. These mailers can only be used within the 48 contiguous states.

Note: Florida inspection packets include a **Clinical Laboratory Personnel Roster**. During the on-site inspection, the inspector must verify that all State of Florida employee licenses for clinical laboratory personnel are current and displayed. The Personnel Roster form must be signed by the applicable inspector. The State of Florida does not require the verification or display of licenses for waived Point-of-Care Testing.

Oregon laboratory inspectors should verify the specialty/subspecialties listed by the laboratory and that the State Certificate is displayed in a prominent place.

Assembling the Inspection Team

The team leader assembles an inspection team appropriate for the size and scope of the laboratory. Selecting an appropriately sized team affects the efficiency of the inspection, the degree to which routine laboratory activities are interrupted during the inspection, and the cost of administering the accreditation program.

Upon receipt of the Inspector's Inspection Packet, the team leader should **immediately review** the materials to determine the number of inspectors, as well as whether specific expertise is needed. The Inspector's Inspection Packet includes information regarding the size of the previous inspection team, and recommends the number of inspector days needed to perform the inspection, based upon the disciplines and test volumes declared by the laboratory. Particular expertise is invaluable if the volume of testing is very high or if the level of testing is unusually sophisticated. When planning for the inspection of large or multi-site laboratories, consider the efficiency of spending more than one day on-site with a smaller team, rather than taking a team large enough to complete the inspection in one day. Particularly with multi-site laboratories, each section supervisor may be responsible for more than one site, and may therefore not be available at more than one site during a one-day inspection.

Generally, one inspector is needed for the Laboratory General inspection, and one for each of the following checklist combinations: Hematology and Urinalysis; Chemistry and Toxicology (when chemistry, special chemistry, and toxicology analyses are performed); Microbiology and Immunology; and Anatomic Pathology and Cytopathology. If the laboratory does not have a donor center, Transfusion Medicine can be combined with another checklist, such as Immunology or Point of Care. Adjustments to the number of inspectors should be made based upon the experience of the inspectors and the extent of testing in the laboratory. All inspectors should be familiar with the safety and test method validation requirements in the Laboratory General Checklist.

For a large full-service laboratory, such as a university hospital laboratory, more than one inspector may be required to inspect the Laboratory General Checklist. Inspectors assigned to other checklists may be able to assist the laboratory general inspector by inspecting the computer, water quality, glassware washing, and safety requirements. If the laboratory delivers donor activities and transfusion activities, an additional transfusion medicine inspector may be needed to complete the inspection in one day. If the laboratory offers microbiology services in all subdisciplines (bacteriology, mycobacteriology, mycology, parasitology, and virology), two inspectors may be required to complete the inspection in one day.

Fewer inspectors will be required for a laboratory with a very limited test menu. Often only a single inspector is required to inspect testing when the Limited Services checklist is used.

The team leader's two major responsibilities are the overall supervision and time management of the team throughout the inspection process, and the completion of the Team Leader Assessment of Director & Quality Checklist, along with the interviews that are a part of that process. Because of this, **the team leader is strongly encouraged to be judicious in taking on other inspection responsibilities and, at most, inspect with only one other checklist.**

Inspection Team Members:

- Must have expertise in their assigned inspection area. This enhances the peer review aspect of the inspection experience, as well as the quality of the education received. The team leader is responsible for ensuring that all inspectors are knowledgeable about the areas they inspect.
- Must be chosen from the list of specialty inspectors provided in the Inspection Packet if the laboratory being inspected requires a cytogenetics, flow cytometry, histocompatibility, or molecular pathology inspection.
- May include medical technologists, cytotechnologists, histotechnologists, clinical scientists, laboratory supervisors, laboratory managers, pathology residents and fellows, and pathologists.
- Can be located using the CAP inspector database. Lists of qualified inspectors may be obtained from the CAP office by calling 800-323-4040, extension 7380, or 847-832-7380.
- Cannot inspect a laboratory or facility for which he or she has provided or is likely to provide consultative services, as stated in the CAP's *Standards for Laboratory Accreditation*.
- Must not be engaged in close personal, family, business or professional relationships with any personnel in a laboratory that the inspector inspects.
- Are trained in the inspection process (see Preparing for the Inspection: Team Member Training Options on page 19).
- **Should review the information supplied by the team leader from the inspector's packet**, including the *Laboratory Accreditation Manual*, laboratory activity menu, instrumentation and equipment lists, Previous Deficiency Report, Variant PT Performance by Laboratory Report (if applicable), test volumes, section personnel, Team Member Inspection Planner (see Appendix K on page 134), and applicable checklists **several weeks before the inspection** in order to be prepared to perform a thorough and efficient inspection. **Each inspector must also be familiar with the safety and test method validation requirements in the Laboratory General Checklist.**

Arranging the Inspection Date

This information applies only to announced inspections that will occur for laboratories seeking initial accreditation, and for RLAP, FDT, and international laboratories.

After accepting the assignment for these laboratories, the inspection team leader should arrange the inspection date. (See the Team Leader Inspection Planner [Appendix J] for details [see page 131].) To arrange the inspection date, the team leader must:

- Contact the laboratory director(s) within two weeks of receiving the Inspector's Inspection Packet. Contact ALL directors if special function laboratories are to be inspected in conjunction with the main clinical laboratory. The inspection date must be mutually agreeable to all lab directors.
- Ensure that the **inspection occurs within the 30 calendar days before the laboratory's accreditation anniversary date**. A mutually acceptable date is preferable; however, the inspection is scheduled at the convenience of the inspector.
- Notify the Laboratory Accreditation Program at the CAP office of the inspection date and the number of inspectors. Contact LAP Operations by telephone at 800-323-4040, extension 6055, or 847-832-7000, extension 6055, or by fax to 847-832-8171, or by mail, or by e-mail to accred@cap.org.
- **Send a courtesy letter to the laboratory director(s)** indicating the inspection date, projected schedule, team listing, special requests (e.g., histology slides for review) and preliminary instructions regarding availability of documentation (personnel and training records, procedure manuals, proficiency testing results, test validation studies, quality control and maintenance records, and a sampling of completed case records (as applicable). **See an example of the template letter in Appendix D (see page 105), which can be downloaded from the "Your Inspection Resource" CD-ROM in the Inspector's Inspection Packet**.

Arranging Inspection Team Travel

The CAP will assist the inspection team in meeting its travel needs. **If air travel or more than 10 hotel nights are required, arrangements must be made through the CAP Travel Desk.** Their agents can be reached at 800-323-4040 or 847-832-7000, extension 7800, from 8 AM to 5 PM Central Time. Alternatively, you may fax to 847-832-8800 or send an e-mail to captraveldesk@cap.org 24 hours a day.

The five-digit Inspection Instance (II) identification number of the laboratory to be inspected must be given to the agent when booking travel. Provide the inspector names that **exactly** match the names on photo identification that they will use for traveling. The College encourages early booking in order to obtain favorable rates. When planning for the inspection, allow for a sufficient number of days to conduct a quality inspection. If a team member needs to change his/her ticketing for the return trip, the CAP Travel Desk agents should be contacted as soon as possible.

The CAP Travel Desk agents can also arrange hotel accommodations and rental cars, if applicable. With four- to six-weeks notice, the travel desk can negotiate a master account to cover the room rates and tax. Inside the U.S., insurance should be declined for rental cars. Outside the U.S., the inspector should purchase the rental car insurance. Refer to Appendix F (see page 112) for additional information concerning travel planning for inspections at facilities with multiple sites.

Requests for Inspection Delays

CLA policy requires that laboratories performing patient testing be prepared for inspection at any time. Any problems encountered in scheduling inspections should ***immediately*** be brought to the attention of the State or Regional Commissioner for resolution.

AABB Coordinated Inspection

- Once notification is received from AABB that an AABB inspector has been assigned, the CAP will provide the name and telephone number of the CAP team leader to the AABB inspector via a letter. The letter includes detailed instructions and information to help ensure that the inspection goes smoothly.
- When the laboratory's reapplication is complete, the CAP will mail an inspector packet to the AABB inspector containing the Transfusion Medicine and Laboratory General Checklists, an Inspector's Summation Report (ISR) form, instructions, and a return envelope.
- The AABB inspector should contact the CAP team leader to see if concurrent unannounced inspections are possible. If possible, the AABB inspector will join the team on the inspection day**.**
- If the AABB inspection cannot be concurrent with the CAP inspection, the AABB inspector may perform a separate unannounced inspection of the blood bank. The inspection date should occur before the CAP anniversary date.
- In either case, concurrent or separate inspections, the AABB inspector should notify the CAP of the inspection date.
- Following the AABB inspection, the completed CAP Transfusion Medicine ISR must be returned to the CAP in the envelope provided.

The CAP team leader should not hold his/her report to await the AABB inspector's report. The CAP accreditation decision will occur only when inspectors from both organizations have submitted the inspection findings to the CAP.

Each organization (CAP and AABB) makes separate accreditation decisions, and one organization's decision does not affect the other.

CONDUCTING THE INSPECTION: GENERAL PRINCIPLES AND MEETINGS

General Principles: How to Inspect

Preparing to Inspect: The inspector must be thoroughly familiar with the checklist(s) that will be used during the inspection. Prior to the inspection, each inspector should review their assigned discipline-specific checklist(s) and the Laboratory General Checklist. **Requirements in the Laboratory General Checklist apply to every laboratory section, and each inspector will be observing for compliance in the areas of test method validation, safety, and the physical environment.** If the intent of any checklist question is not clear, CAP staff can offer further explanation or interpretation before the inspection through the accreditation e-mail site (accred@cap.org), or before or during the inspection at 800-323-4040, option 2, option 2, or extension 6065.

Review of the Activity Menu: The laboratory's activity menu and instrumentation lists help the inspector understand the type and scope of testing the laboratory is performing. These should be provided by the team leader along with the checklists to be used. The inspection checklists are customized based on the laboratory's activity menu. If an inspector discovers testing being performed that is not included in the activity menu, CAP staff should be contacted so that appropriate action can be taken.

How to Begin the Inspection: Each inspector should bring photo ID. **For unannounced inspections, arrive 30-60 minutes sooner than for an announced inspection.** This allows enough time to get through security, if applicable, and give the lab sufficient time to locate key personnel and make other arrangements. The inspection team leader will present the letter supplied by the CAP verifying that the inspection is to occur on that day under the direction of the team leader.

After introductions and a brief overview of the day's schedule, many inspections begin with a brief tour of the laboratory. Many inspectors find it helpful to "follow a specimen" through the laboratory, which addresses the pre-analytic, analytic, and post-analytic aspects of laboratory testing. This process is generally followed by review of the laboratory's documentation.

What to Look At: The inspector observes a laboratory's activities and reports the findings. The inspector will look at all types of documentation, including procedure manuals, quality control and proficiency testing records, instrument maintenance records, and test method validation studies. As the inspector examines procedures and documentation, it is a good practice to make a note of questions to be asked while observing the laboratory section.

Procedure manuals should be complete, current, available to staff, accurate, reviewed by the laboratory director or a documented designee, and should describe good laboratory practices. QC and PT records must be complete, reviewed, and show evidence of troubleshooting and error resolution. PT must be performed for every test performed by the laboratory, regardless of test complexity. Records of validation testing must be available to the inspector regardless of when the laboratory implemented the test, and the records must be available for two years after the test or method is retired. For each non-waived test, the laboratory must have data on the test's accuracy, precision, analytic sensitivity, interferences, and reportable range as applicable.

In addition to examining documentation, the inspector will observe laboratory practices to verify that actual practice matches the written policy or procedure. The inspector should ask probing questions of the laboratory staff, technical staff, and supervisors, and must spend a significant amount of time in the laboratory observing staff performing the testing.

How Much to Look At: Since it is not possible for the inspector to review every procedure, quality control record, or piece of analytic data, the inspector should consult the laboratory's activity menu and selectively focus on areas of highest and lowest test volume, likely problem areas, and test results with the highest impact on patient care. It is usually more instructive to review the records for 10 analytes or procedures comprehensively than to review the records for 50 tests superficially. If applicable, the inspector's packet includes a Variant Proficiency Testing Performance by Laboratory Report that identifies, by analyte, all of the PT scores below 100% during any of the last six testing periods. Correlate any PT problems to QC or maintenance records from around the same time interval. Be thorough when reviewing these representative records, selecting data from the beginning, middle, and end of the period since the last on-site inspection. Be comprehensive, reviewing records in the pre-analytic (order entry, and specimen collection, processing and transport), analytic (procedures, QC, PT, instrument setup, and maintenance) and post-analytic (reports, reference ranges, critical value notification) categories. If problems are discovered, review similar records for additional analytes.

Using the deficiency report from the last inspection, the inspector must verify that all previous deficiencies have been corrected, paying particular attention to recurring deficiencies.

How to Obtain Information: Courtesy and consideration are important. Laboratory personnel should be interviewed, not interrogated. Open-ended, probing questions that require more than a yes/no answer are preferred, such as "Could you explain how you track QC data?" or "What type of follow-up do you perform when your PT results are evaluated as unacceptable?" Do not just reiterate the checklist question verbatim; rephrase the question, using language such as "Could you show me how you…" or "Explain the system you use for …", or "How do you document that…."

The inspector should spend time in the laboratory observing the testing process and asking questions of bench technologists and supervisors, rather than spending the majority of time in a room reading documents. Reviewing documents, observing to see if practice matches policy or procedure, and asking related questions all play an important role in obtaining accurate information about laboratory practices. Techniques used by successful inspectors include "following the specimen" from receipt through processing, testing, and on to result reporting.

When to Cite a Deficiency: The laboratory practices must meet the intent of the checklist question, but the laboratory does not have to do things exactly as they are done in the inspector's laboratory. There are many ways to accomplish the same objective. Cite a deficiency if there is no policy or procedure; if it is not being followed or documented as written; or if there is no record of review or corrective action. In the situation where documentation or records are incomplete, the inspector must judge whether the degree of partial compliance is likely to have adversely affected patient care or worker safety. If so, a deficiency must be cited. If the checklist item applies but the laboratory does not address it in any way, the laboratory is not in compliance. Do not be afraid to cite a deficiency. Never give a recommendation instead of a deficiency if the laboratory is not in compliance. When an inspector gives a recommendation instead of a deficiency in a situation where the laboratory is clearly deficient, the CAP technical staff or the Regional Commissioner will convert the recommendation to a deficiency and ask the laboratory to respond to and correct the deficiency. Remember that the goal of the inspection is laboratory improvement.

How to Cite a Deficiency: Be specific. State the finding, not the checklist question! On the ISR, write down the checklist item number followed by the exact nature of the deficiency. Clearly indicate the specific reason the laboratory is deficient and what needs to be changed or modified to correct the deficiency. Write/print legibly.

When to Give a Recommendation: A recommendation is a suggestion for improvement; for instance, when a laboratory is in compliance but it can improve its process. A recommendation may not always pertain to a specific checklist item, but could relate to the way the laboratory is doing something or keeping records. The laboratory is not obligated to respond to or implement a recommendation. Do not give a recommendation rather than a deficiency just to be "nice." If a laboratory is not in compliance, it is deficient. A recommendation that should have been cited as a deficiency will be changed to a deficiency by CAP staff, and a deficiency response will be required from the laboratory.

When Differing Interpretations of a Checklist Item Occur: The inspector and the respective laboratory representative are encouraged to **get together** and **call the College's technical support line at 800-323-4040, extension 6065, during the inspection.** A three-way dialogue between the inspector, laboratory, and Laboratory Accreditation Program technical specialist often helps clarify the intent of the checklist item. This can result in fewer improperly cited deficiencies and laboratory deficiency challenges post-inspection.

Inspection Techniques – Key Points

The following information is present at the beginning of each checklist, so that every inspector has access to the techniques used by highly experienced and effective inspectors. These inspection techniques help elicit additional useful information about the laboratory being inspected. The techniques represent tried and true techniques such as following a specimen through a laboratory, asking probing questions of laboratory supervisors and bench technologists, and performing an in-depth analysis of specific analytes. When used in conjunction with a review of written policies, procedures, and records, these techniques can help the inspector quickly gain a valid perspective of the overall quality of a particular laboratory section.

READ – OBSERVE – ASK

I. READ – OBSERVE – ASK are methods of eliciting information during the inspection process. These 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, reviewed, and describe good laboratory practice. As you read the laboratory's documentation, make notes of any questions you may have, or processes you would like to observe.

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 previous deficiencies have been corrected.

Use the following techniques:

- **Observe: 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 five to 10 checklist questions at a time.

    - 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. Do not ask the checklist questions verbatim or in a sequential fashion. 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 related to the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including the use of 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 but are not limited to 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 by Laboratory Report.

***To evaluate pre-analytic and post-analytic issues**:* Choose a representative specimen and "follow" the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the pre-analytic and post-analytic categories.

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

III. Verify that Proficiency Testing Problems 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 around the same time interval. 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.

Using the Team Leader Assessment of Director & Quality Checklist

This checklist **must be completed by the team leader or a team member who is qualified and trained to be a team leader. The purpose of this checklist is to evaluate the qualifications of the laboratory director and the effectiveness of the director in implementing the *Standards* of the Laboratory Accreditation Program, including the laboratory's quality management plan. The checklist** includes questions pertaining to laboratory director responsibilities that previously appeared in the Laboratory General Checklist. The TLC also includes questions to evaluate the overall performance characteristics of the laboratory. This tool makes it possible for the team leader to more easily conduct a thorough assessment of the overall effectiveness of the laboratory's quality management program and includes instructions on how to conduct interviews with the laboratory director, hospital administrator and chief of the medical staff. It assists the team leader in evaluating aspects of the laboratory that are at the core of quality: the laboratory director's responsibilities, the quality management plan, and the laboratory's relations with the institutional medical staff and administration.

The following information regards the meetings with the laboratory director, hospital administrator, and representative of the medical staff. These meetings are conducted by the team leader and will provide some of the information needed to complete the new Team Leader Assessment of Director & Quality Checklist. The interviews that occur at these meetings are essential parts of the inspection. If, for any reason, an interview cannot be conducted, the team leader should discuss the circumstances in the Inspector's Summation Report.

Meeting with the Laboratory Director

Purpose: To determine whether or not the laboratory director has sufficient responsibility and authority for the operation of the laboratory. A minimum of 15-20 minutes should be allowed for the meeting. If the director is not present during the unannounced inspection, this interview may be conducted by telephone. In addition, on-site conversation with technical staff, administration, and the CMO may be used to validate the director's involvement in laboratory operations.

The interview is an opportunity to:
- Evaluate the director's activities as listed in the Team Leader Assessment of Director & Quality Checklist and the *Standards for Laboratory Accreditation*.
- Review any problems that the inspection experience might serve to resolve (e.g., space problems, staffing shortages).

Meeting with the Hospital Administrator/Chief Executive Officer (CEO)

For hospital-based laboratories, the inspector should meet with the hospital administrator/CEO. Approximately 15-20 minutes should be allowed for the meeting. It is a good idea not to schedule the meeting for early in the day, since the team leader should have a sense of the laboratory's operations first. For independent laboratories, the inspector should meet with an executive from the laboratory organization.

Purpose: To extend the College's appreciation for participating in the accreditation program and to record an evaluation of the laboratory from the administration's viewpoint.

The interview is an opportunity to:
- Ascertain the administration's perception of the laboratory service.
- Address the effectiveness of the working relationship among the laboratory, its director, and the hospital administration.
- Identify any areas of conflict.
- Educate administration on the value of the CAP Laboratory Accreditation Program.

Points to cover during the interview are:
- The goals of the CAP Laboratory Accreditation Program: Education, regulatory compliance, and laboratory improvement.
- Inspection method: Two-year accreditation cycle; use of active laboratory professionals as inspectors; educational value to inspector and inspected laboratory.
- The role of proficiency testing in the program (given the cost of proficiency testing relative to accreditation itself, it is particularly important to point out that it would be required irrespective of the accrediting agency).

The interview should include a discussion of all laboratories being inspected (i.e., special function and satellite laboratories). **Discussion of the laboratory's financial and/or contractual arrangements is prohibited.**

When speaking with the hospital administrator, the team leader should ask if the laboratory service level is appropriate to the requirements of the institution. The team leader should ask how the pathologists participate in hospital-wide committees, how effective they are in working with the medical and administrative staffs, and if they meet the expectations of the administration.

The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Meeting with a Representative of the Medical Staff

For laboratories associated with organized medical staffs, it is important for the team leader to interview the chief of the medical staff (or other knowledgeable medical staff representative, such as the chief medical officer, or a physician who uses the laboratory's services frequently).

The team leader should allow for a 15-20 minute discussion and should have an understanding of the laboratory's operations beforehand.

Purpose: To determine whether the laboratory director and the laboratory staff have established an effective working relationship with the medical staff and are effectively supporting patient care.

The interview is an opportunity to:

- Evaluate how effectively the scope, quality, and timelines of the laboratory services meet the patient care needs of the hospital.
- Assess the contribution of the pathologists and laboratory staff to teaching conferences and meetings.
- Determine the cooperation of medical staff and pathologists in problem resolution.
- Judge the medical community's perception of the pathologists.

When meeting with the chief or other active member of the medical staff, the team leader should inquire about the scope, quality, and timeliness of laboratory services. The team leader should ask the medical staff representative for input on pathologist participation in medical staff committees, participation in institutional quality management (performance improvement) and patient safety activities, and participation in teaching conferences. The discussion should include all laboratories being inspected, including special function and satellite laboratories.

The inspector may record information from this interview in Part A of the Inspector's Summation Report.

Meetings with Direct Health Care Providers

The inspector should visit certain direct patient care areas during the course of the inspection. For example, if transfusion services are provided, observation of a transfusion should occur, or point-of-care-testing should take the inspector to the patient bedside. If the inspector wishes to visit other direct patient care areas, this should be requested of the laboratory director on the day of the inspection.

Purpose: To determine how the medical, nursing, and clerical staff use the laboratory data and communications.

The visit should include:

- Observation of phlebotomy if performed by laboratory personnel;
- Review of laboratory portions of patient charts for clarity of presentation;
- Assessment, through interviews, of laboratory responsiveness to clinical needs; and
- Identification of concerns that can be relayed to the laboratory director.

Meetings with Clients of Independent Laboratories

Meetings with clients during an inspection of an independent laboratory **are not required.**

Other Meetings

For hospital laboratory inspections, it may be useful to meet with the institutional quality assurance manager (sometimes called Quality/Risk Management). This person may have insights into the laboratory's input into safety and other issues that put the institution at risk.

Inspecting Additional Activities, Disciplines, and Laboratories

Additional Activities Not Reported at Application/Reapplication

If the inspector observes that a laboratory section unit is performing activities NOT reported to the LAP during application/reapplication, these activities may be inspected as time permits. Contact the CAP immediately and, if necessary, additional checklist questions will be faxed to you. The inspector should perform a thorough inspection of these activities, and the inspector must verify that the laboratory is enrolled in the appropriate proficiency testing. A note regarding these additional activities should be placed in the Inspector's Comments section of Part A of the ISR, along with whether or not they were inspected.

Additional Disciplines Not Reported at Application/Reapplication

If the inspector notes that testing not reported to the LAP is being performed that involves an additional discipline or checklist, the inspector should contact the CAP immediately to determine if inspection of that discipline should proceed. This pertains only to testing being performed under the same CLIA number of the laboratory that is being inspected. If there is someone on the inspection team with the expertise to inspect the area, and if the CAP determines that the inspection of this testing may proceed, a customized checklist can be faxed to the inspector or the necessary additional checklist can be printed from the CD-ROM that is included in the Inspector's Inspection Packet. The inspector must verify that the laboratory is enrolled in the appropriate proficiency testing for these analytes/activities. A note regarding this additional discipline should be placed in the Inspector's Comments section of Part A of the ISR, along with whether or not it was inspected.

Additional Laboratories Not Reported at Application/Reapplication

Testing performed under a different CLIA number or special function laboratories that are under separate administrative and professional direction (e.g., blood gas laboratory, pediatric hematology laboratory) and have not applied in advance for inspection **will not be inspected.** The inspector should inform the director that a formal application must be made through the CAP office. An inspection will be scheduled at a later date.

INSPECTING THE LABORATORY SECTIONS

Note: Checklists are frequently revised and requirements may change. When information in this manual is not consistent with the currently published checklists, the currently published checklists contain the most accurate and up-to-date accreditation requirements. During the inspection, the inspectors must use the paper checklists supplied in advance by the Laboratory Accreditation Program.

Some general requirements are applicable to all laboratory disciplines, sections, or departments. Some of these requirements are found in each of the discipline-specific checklists, and some are in the Laboratory General Checklist. **Requirements common to all sections of the laboratory are discussed in the next section.** For additional requirements specific to each individual discipline, consult the discipline-specific section of this manual.

Requirements Common to All Laboratory Sections

Proficiency Testing: Proficiency testing (PT) is integral to the CAP Laboratory Accreditation Program, and is required for every analyte for which the laboratory reports patient sample results. The CAP audits PT participation to assure that accredited laboratories participate in PT as appropriate. The audit is based on the activities that are reported by the laboratory to the CAP, and are therefore present on the laboratory activity menu. Effective participation in proficiency testing consists of the investigation of any result that is other than acceptable, including analytes that are not graded by the PT provider, and implementation of appropriate corrective action(s). If the laboratory fails to meet the requirements of the LAP, the College may ask the laboratory to cease testing for the analyte for a minimum of two proficiency testing events or until the laboratory can demonstrate acceptable performance in proficiency testing. If the laboratory refuses to cease testing, its accreditation will be in jeopardy. The inspector will devote a significant portion of the inspection to the laboratory's PT.

It is helpful when records are organized such that evaluation reports and participant summaries are collated with original worksheets and instrument tapes, and all decisions and actions are clearly annotated. Participation in PT programs accepted by the Commission on Laboratory Accreditation is required for most analytes. Approval as a PT provider by CMS under CLIA'88 does not automatically constitute acceptance by the College for purposes of accreditation. Not all CAP Surveys are required for accreditation. The PT Enrollment Guide that lists the analytes for which PT is required is posted at the CAP Web site at www.cap.org. Any questions may be directed to the Proficiency Testing Specialists in the CAP office at 800-323-4040 option 2# (LAP), 5# (Proficiency Testing Exception Summary).

If enrollment in a PT program is not required for a particular analyte, the laboratory must use an alternative method to assess its analytic performance for that test, and this must be performed at least every six months. Alternative assessment methods include use of material from a PT program that is not required; splitting samples with a reference or other laboratory; challenging the analytic system using previously assayed material; and clinical validation by chart review. It is the responsibility of the laboratory director to define such procedures, including evaluation criteria, in accordance with good scientific and clinical laboratory practice. The laboratory must also have a procedure for assessing its performance on PT challenges that were not graded (for instance, because of lack of consensus, or because the laboratory either submitted its results after the cut-off date for receipt, did not submit results, or did not submit an appropriate method code). The laboratory director must also ensure that no proficiency testing specimens are referred to another laboratory, and that there are no interlaboratory

communications about proficiency testing samples until after the date by which the laboratory must submit results to the proficiency testing provider.

Inspectors must review the performance of PT, including alternate procedures that are used instead of formal external PT. Several items are included in the inspection packet to assist the inspector. The Variant Proficiency Testing Performance by Laboratory Report lists all reported scores below 100% for the preceding six PT events.

The laboratory must integrate all proficiency testing samples within the routine workload. Personnel who routinely test patient/client samples must analyze the PT samples, using the same testing protocols as for patient/client samples. Replicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner. If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method.

The educational purposes of proficiency testing are best served by a rotation that allows all technologists to be involved. Records of these studies must be maintained and can be an important part of the competency and continuing education documentation in the personnel files of testing personnel.

The inspector may ask to see specific documentation of performance troubleshooting as well as clear evidence that a problem was corrected. Discussions could involve issues of QC performance during or adjacent to the same performance period, calibration accuracy/frequency or calibration verification, and validation of the analytical measurement range. There must be documentation that any problems discovered through PT were identified and corrected, and documentation that the laboratory director or designee has reviewed all of the results and evaluations. In addition to reviewing follow-up on "unacceptable" results, the inspector will confirm that PT records are complete, that PT challenges have been handled like patient testing as closely as possible, and that any evident bias in PT results has been recognized and addressed.

Sometimes the required PT challenges are not graded. The reason is always footnoted on the Evaluation Report or available from the PT provider. The laboratory must follow up whenever a required challenge was intended to be graded. Suggestions for investigating non-graded PT results are given in Appendix I (see page 129). The inspector will affirm that formal PT or alternative assessment is performed for every analyte and that all corrective actions make sense.

Investigating PT Failures and Biases:

- Check reporting forms and records of sample preparation and testing for mistakes.
- Review QC performance, instrument calibration, and reagent performance prior to, during, and after the time of PT performance.
- Verify that the PT material was processed in the correct instrument mode and reported in the correct units.
- Contact the instrument/reagent manufacturer for assistance.
- Repeat the PT challenge, if possible, using a different reagent lot or instrumentation system.

Corrective Action following a PT Failure:

- Repeat instrument function or testing system verification.
- Increase the frequency of calibration.
- Revise or replace the analytic procedure.

- Design a process to double-check clerical entries prior to submitting PT results.
- Retrain testing personnel in the proper procedures for sample preparation, testing, and reporting.
- Maintain clear records of all corrective actions taken.

For more ideas, see CLSI Guideline GP27-A2 "Using Proficiency Testing to Improve the Clinical Laboratory [2007]."

Quality Management: The laboratory must have a planned and systematic program for the monitoring and evaluation of the quality and appropriateness of its patient care services, for resolving identified problems, and for ensuring that the program is implemented throughout all laboratory sections by the director.

The laboratory must have a procedure that encourages employees to communicate any concerns or complaints with respect to the quality of patient testing and safety. The investigation and analysis of employee complaints and suggestions, with corrective and/or preventive action as appropriate, should be a part of the laboratory quality management plan and specifically addressed in laboratory quality management records. During the on-site inspection, the inspector will review records of employee input and follow-up by laboratory management.

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

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

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

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

Visit the CAP Web site to hear the "Your Quality Improvement Plan" and "Patient Safety Goals" audioconferences.

Quality Control: The quality control checklist questions are designed to determine whether QC procedures are clearly defined, whether the laboratory director uses the quality control program to evaluate performance, and if corrective actions are taken when necessary. In most cases, for quantitative testing, two levels of quality control must be performed each day of testing. Qualitative testing requires that a positive and negative control be run each day patient testing is performed. Electronic and onboard internal QC is acceptable as part of a quality control plan. The laboratory must determine QC tolerance limits, and corrective action must be defined and documented.

Before patient results are reported, QC data must be judged acceptable. The laboratory director or designee must perform secondary review QC data at least monthly. Beyond these specific requirements, a laboratory may optionally perform review more frequently at intervals that it determines appropriate. The laboratory must follow State requirements if these are more stringent than those of the CAP Laboratory Accreditation Program.

Reagents: Reagents must be properly labeled with the following elements: content and quantity, concentration or titer, storage requirements, date prepared or reconstituted, and expiration date. This includes secondary containers. These elements may be recorded in a log (paper or electronic), rather than on the containers themselves, provided that all containers are traceable to the appropriate data in the log. There is no requirement to indicate on the label the date received or placed in service. The laboratory must use components of reagent kits only with other kits that are of the same lot number, unless otherwise specified by the manufacturer. New lots of reagent must be checked against old lots, or with suitable reference material, before or concurrently with being placed into service. For quantitative tests, reagent validation is most reliably performed by assaying the same patient specimens with both the old and new reagent lots. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative patient sample from the old reagent lot against the new reagent lot. Reagents must not be used after their stated expiration date.

Waived Test Requirements*:* Certain checklist requirements are now different for waived tests versus non-waived tests.

For waived tests, follow manufacturer instructions for:
1. Test procedure and method validation
2. Reagent storage, handling and validation
3. Quality control performance
4. Calibration, calibration verification, analytical measurement range validation, and clinically reportable range

For waived tests, the following are not required (unless required by the test manufacturer):
1. Lot-to-lot reagent validation
2. Correlations between waived instruments and between waived instrument and main laboratory instrument
3. Initial AMR validation and six-month interval validation

Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and non-waived tests.

Procedure Manuals: Each section of the laboratory must have a complete procedure manual available to, and used by, personnel at the workbench. Elements of the procedure manual should include, as applicable: Test principle, clinical significance, specimen type(s), required reagents, calibration, quality control, procedural steps, calculations, reference intervals, and interpretation. Laboratories may use CLSI document GP2-A4, *Clinical Laboratory Technical Procedure Manuals* (Wayne, PA: CLSI, 2002) as a guide, but need not copy its exact format. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures and to ensure that all significant information and instructions are included. Direct observation of procedures during the on-site inspection allows the inspector to verify that actual practice matches the contents of the procedure manuals.

The use of a package insert provided by the manufacturer is not acceptable by itself in place of a procedure; however, such inserts may be used as part of a procedure if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. Quality control materials and acceptance criteria, reference ranges, critical values, and reportable ranges are aspects of a procedure that often result in customization of the written procedure by the individual laboratory. In all cases, appropriate review must occur.

Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that a complete manual is available for reference and the card file or similar system corresponds to the complete manual and is subject to document control.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed [manual or electronic], and there is documentation of periodic review). There is no need to print a paper copy for the inspector if electronic procedures can be viewed during the inspection.

There must be documentation of at least annual review of all policies and procedures by the current laboratory director or designee. The director is responsible for ensuring that the collection of technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. **If annual review is delegated, the designee(s) should be specified in writing.** Paper/electronic signature review must be at the level of each procedure or as multiple signatures on a table of contents or listing of named procedures. A single signature on a title page or index of all procedures is not sufficient documentation that each procedure has been reviewed. A signature or initials on each page of a procedure are not required.

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, or AMR), 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.

The laboratory must retain records of method performance specifications while the method is in use, but in no case for less than two years.

***Instruments and Equipment**:* Checklist questions concerning general instrument requirements are found in most checklists and address glassware and pipettes, automated pipettes and dispensers, thermometers and temperature-dependant equipment, centrifuges, and analytical balances.

- Glassware and pipettes: Volumetric flasks must be of certified accuracy (i.e., Class A category of the National Institute of Standards and Technology [NIST]). All non-certified glassware must be checked for accuracy before being placed into service. Volumetric pipettes should be stored separately as to size and type. The use of disposable plastic pipettes should be limited to situations where the accuracy and precision of calibrated glass pipettes are not required.
- Automated pipettes and dispensers must be checked for accuracy (by colorimetric, gravimetric, volumetric, or other means) before being placed in service, and results documented. Accuracy and reproducibility must be verified at laboratory-defined, periodic intervals. The use of dispensers must be limited to measurements not requiring volumetric accuracy.
- Thermometers: An appropriate thermometric standard device of known accuracy (NIST-certified or guaranteed by the manufacturer to meet NIST standards) must be available. All non-certified thermometers must be checked against an appropriate thermometric device before being placed into service. Temperatures should be checked daily for all temperature-dependent equipment, such as refrigerators, freezers, water baths, and incubators. Tolerance limits must be specified for all temperature-dependent equipment.
- Centrifuges should be clean and properly maintained. There should be a documented protocol and schedule for maintenance (e.g., cleaning, changing brushes). The operating speeds of all centrifuges should be checked periodically.
- Analytical balances should be cleaned, serviced, and recalibrated only by experienced personnel. Balances should be mounted such that vibrations do not interfere with the readings. Standard weights of an appropriate ANSI/ASTM class should be available for checking accuracy. Weights should be well maintained (clean, no rust). Accuracy checks should be documented.

Consult the discipline-specific checklists for instrument and equipment requirements other than the general requirements discussed here.

Visit the CAP Web site Virtual Library of Audioconferences to hear the “Solutions for the Most Common Deficiencies” audioconference.

Laboratory General (GEN)

The Laboratory General Checklist covers the entire laboratory and is used with each inspection. Issues such as management, personnel, specimen collection, computer function, inventory control, safety policies, QM, and general QC procedures are included. **Inspection of a discipline-specific area also includes the use of all applicable portions of the Laboratory General Checklist**. To accomplish this, each inspector must be knowledgeable about the Laboratory General Checklist requirements. To this purpose, the **team leader**, as applicable, **should provide individual team members with copies of the appropriate sections of the Laboratory General Checklist.**

Ways the Discipline-Specific Inspector Can Assist the Laboratory General Inspector: Do the following as you inspect your discipline specific section (e.g., Microbiology, Immunology, Transfusion Medicine, etc.). Talk about your findings with the Laboratory General inspector at lunch or before the presummation conference.

1. Observe for:
    a. Posting of safety policies/procedures
    b. Evacuation routes posted
    c. Ergonomics of devices in use
    d. Elimination of exposure to blood borne pathogens during phlebotomy and laboratory testing
    e. Use of natural latex rubber in gloves and other products
    f. Use and care of disposable gloves and facitilities/materials for hand decontamination after gloves are removed
    g. Proper personal protective devices when handling corrosive flammable biohazardous and carcinogenic wastes
2. Report what you saw during your brief "lab tour" in the early morning, even if only on your way to the section you will be inspecting. Team members will notice different things.
3. Safety: Observe for proper
    a. Use of personal protective equipment (PPE)
    b. Segregation of contaminated trash/sharps
    c. Use/disposal of gloves, hoods, and protective eyewear
4. Laboratory computer services – observe for password security, posting of passwords near CRT terminals, sharing of passwords.
5. Orphan testing – observe for tests performed in multiple or an illogical department or section. For example, Group A strep testing could be performed in microbiology, immunology, or other sections. Be sure to alert the discipline specific inspector of the more traditional location, and use their expertise to inspect those tests.
6. Compare the lab's activity menu to their procedure manuals. You may find some tests they perform very infrequently that they have failed to report to the CAP.
7. Space – note any situations that you believe endanger the quality of the test result or the health and safety of the lab employees (for instance, lack of benchtop space to open a procedure manual, storage that is underfoot, blocked hallways, etc.).

Personnel: Several randomly selected personnel files should be reviewed to determine whether the required information is included. Technical personnel records must include; a s**ummary of training and experience; formal certification or license, if required by the state**; **description of current duties (may be generic to a position); records of continuing education**; **records of radiation exposure where applicable; and work-related incident and/or accident records.** Training and experience should be appropriate for the responsibilities of each person. If the qualifications of a supervisor (chief technologist or department head) are in question, concerns should be described in the Inspector's Summation Report. Suggestions related to staffing levels and pathologist coverage issues should be discussed directly with the laboratory director instead of during the Summation Conference.

An effective way to assess training and competency is to concentrate on any problems identified while inspecting a laboratory section. Investigate who was involved in the problem or made the error, and

review the employee's training and competency records to ensure that adequate training or retraining has taken place.

The laboratory director must:

- Meet the qualifications found in the Standards for Laboratory Accreditation.
- Be a physician or doctoral scientist.
- Have sufficient authority to implement the *Standards*.
- Meet the requirements listed in the Team Leader Assessment of Director & Quality Checklist.

Note: The director need not personally discharge all functions. Administrative functions may be delegated to qualified laboratory managers or supervisors. Medical and technical responsibilities may be delegated to other physicians and qualified laboratory personnel. When responsibilities are delegated, written documentation of the designee must be available. If the laboratory director is not qualified to direct any of the individual sections of the laboratory, those sections must be directed by a qualified individual.

Consulting Pathologist

When the director is not qualified as an anatomic pathologist, the services of a qualified consulting anatomic pathologist must be retained. A policy regarding the duties of the consulting pathologist must be in place.

The consulting pathologist must:

- Provide documentation of activities performed and a documented report with evaluation and recommendations in writing for each consultation visit.
- Visit the laboratory as often as required. The CAP does not define any specific frequency.
- Serve as a consultant to the medical staff and play an active role in the educational programs of the laboratory and institution.

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

Specimen Collection: How specimens are collected and handled is critical for valid results. Instructions must be provided for the collection and handling of specimens for all tests. If the laboratory accepts specimens collected by non-laboratory personnel, a typical specimen collection area should be checked for availability of the specimen collection instructions. The inspector must ensure that the laboratory has reviewed its phlebotomy practices relative to specimen blood draw volumes and should examine the documentation that all personnel performing patient blood collection have been trained in the selection and use of equipment, supplies, and collection techniques.

The specimen collector must positively identify the patient before collecting a specimen. The inspector must verify that there is 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.

Review by the laboratory director or designee of the specimen collection/handling manual must occur annually. In addition, the laboratory director or designee must review and approve all changes to the manual before implementation.

Laboratory Transport Services: Specimens received from remote locations outside of the facility in which the laboratory is located, as well as specimens referred by the laboratory to other locations, require transport to the testing laboratory. **There should be a documented tracking system to ensure that all specimens submitted to the laboratory are actually received**. The inspector must verify that the laboratory director has addressed the issues of specimen tracking, personnel training, packaging and labeling, monitoring specimen quality, correcting problems, and improving the performance of clients or offices that frequently submit specimens improperly. The laboratory must package and ship infectious material in accordance with applicable federal, state, and local regulations.

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, 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 at a sending facility must satisfactorily complete certified training in these requirements every two years. **Certified training requirements do not apply to personnel sending samples via private courier.**

Personnel Competency Assessment: The inspector will look for documentation indicating that the laboratory has assessed annually the competency of each person to perform his or her assigned duties, in addition to the six-month evaluation required after hiring. The laboratory should have a documented corrective action plan to retrain and reassess employee competency when problems of employee performance are identified. The inspector will look for evidence that competency has been reassessed and found to be acceptable after the corrective action plan has been implemented.

Computer-Generated Reports: The laboratory's computer system should be able to identify each individual contributing to or editing the released result. The data must be secure and the backup system functional. If reference laboratory data are transcribed, the name of the laboratory that actually performed the test must be on the report; the address of the testing laboratory may be on the report or available in other laboratory records. Revised/amended reports must be clearly marked as such, and must contain both the original and revised/amended data.

Review of Results: A routine system must be in operation to detect clerical errors or unusual laboratory results and must provide for timely correction of those errors. Computer systems that report data are not exempt from this review. The review mechanism must be described in the QC policies and procedures. There is no requirement for secondary daily review of patient test results.

Confidentiality and Read-Back of Patient Orders and Reports: Each laboratory must have a policy that personnel receiving verbal or phone orders must read back the entire order to verify accuracy of transcription. The laboratory must also have a policy with respect to verification "read-back" of critical values that are communicated verbally or by phone. In addition, there must be a documented protocol in place to ensure that patient data are accessible only to those health care personnel who are authorized to review test results. This applies both to results of in-house tests and to results received from outside reference laboratories.

Record Retention: Specimen requisitions (including the patient chart or medical record, if used as the requisition), patient test results and reports, accession records, quality control records, proficiency testing records, and quality management records must be retained for a minimum of two years.

For data transmitted by computer interface (online system), it is not necessary to retain paper worksheets or printouts, so long as the computer retains the data for at least two years. Manual entry of patient result data requires that the laboratory retain all worksheets or printouts for at least two years. Refer to Appendix G for retention information (see page120).

Specimen Retention: Serum and body fluid specimens (excluding urine) must be retained for at least 48 hours. Blood films, permanently stained body fluid slides, and microbiology slides must be retained for at least seven days. Additional detailed requirements or recommendations are found in section-specific checklists. Any deficiencies noted by the inspector must be detailed in the ISR.

Self-Evaluation Documentation: Laboratories must perform a self-evaluation (self-inspection) each year an on-site inspection by the CAP does not take place. The laboratory director must document the occurrence and findings of the self-evaluation. If any deficiencies are found, the laboratory must document the corrective actions.

Conducting the Safety Inspection

Introduction: Questions in the Laboratory General Checklist 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 and should be detailed in the Inspector's Summation Report Part B. Specific questions related to safety features unique to an individual section will be found in the checklist for that section. When a team inspects the laboratory, each member of the team must inspect for safety hazards in that portion of the laboratory for which he/she is responsible.

General Safety: Procedures should be posted or otherwise available to all employees. Instruction in these safe work practices should be a documented part of new employee orientation. The inspector should review the safety manual for completeness. Several items should be selected from the safety manual for interviewing an employee regarding knowledge about safety issues. Under U.S. law, all serious accidents resulting in fatalities or in the hospitalization of three or more employees must be reported to the Occupational Safety and Health Administration (OSHA) within eight hours. Reports of occupational injuries or illnesses that require medical treatment or result in time lost from work must be reviewed as part of the laboratory's QM program to avoid recurrence. This includes every needle stick or sharps injury. An inspector should ask about recent injuries or occupational illnesses and review the adequacy of the follow-up. Non-U.S. laboratories must adhere to locally applicable regulations.

The current laboratory director or designee must review safety policies and procedures annually and also all changes before implementation.

The laboratory should maintain records demonstrating that all laboratory personnel performing patient blood collection have been trained in proper selection and use of equipment, supplies, and collection techniques. This includes phlebotomists at remote sites owned and operated by the laboratory. OSHA now requires employers to select safer needle devices as they become available and to involve employees in identifying and choosing the devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.

Fire Protection: National Fire Protection Association (NFPA) documents may be used as references for fire prevention and preparedness questions. An accredited laboratory must: (1) have an automatic fire extinguishing system; or (2) be separated from a contiguous inpatient facility by fire-resistant construction that has a minimum rating of two hours and class B self-closing door assemblies rated at three-quarter hours; or (3) be located in buildings classified as "business occupancy." In all cases, a fire bell, public address system, or other alarm system must be audible in all sections. This includes lavatories, darkrooms, storage areas, and offices. **Laboratories employing hearing-impaired persons must have other means to alert these individuals, such as a visual alarm system.** The inspector should ask employees if there are areas in which the alarm is difficult to hear. If there is any area where the alarm cannot be heard, the inspector should cite a deficiency. If there is any doubt as to the arrangement of the laboratory area or applicability to fire codes, the inspector should ask to see documentation that the local fire authorities have approved the current arrangement.

Fire drills must be held often enough that all laboratory personnel, from all areas and on all shifts, participate at least once per year. Class B portable fire extinguishers must be located in all areas where flammable or combustible liquids are stored or handled. There must be documentation that all personnel have been properly trained in the use of portable fire extinguishers. This should include actual operation of extinguishers that might be used in the event of an actual fire, unless the local fire authority prohibits this.

Ignitable liquids must be stored properly, and the Laboratory General Checklist specifies the U.S. maxima by laboratory square footage, with consideration of safety cans, safety cabinets, and sprinkler systems.

Electrical Hazards: All laboratory instruments and appliances should be adequately grounded and checked for current leakage before initial use, after repair or modification, and when a problem is suspected. Those that are double insulated are exempted. Tasks may be delegated to biomedical and electrical engineers, but documentation must be present on inspection day, or a deficiency should be cited.

Chemical Hazards: The laboratory must evaluate and document the hazards associated with all chemicals present. The director must have a comprehensive signage and labeling system in use and applied throughout the laboratory. Each hazardous chemical must be labeled with the type of hazard and what to do if accidental contact occurs. Material safety data sheets (MSDS) must be on file for each hazardous chemical.[1] It is acceptable for MSDS information to be electronically available to users, rather than in book format; there is no requirement for paper-based information. However, the MSDS file must be immediately available to all personnel at all times. The inspector may choose to select one or two hazardous chemicals found in the laboratory and question an appropriate employee about the safe work practices that relate to that substance. For laboratories subject to U.S. law, OSHA requires a comprehensive, documented Chemical Hygiene Plan (CHP).[2] All chemicals, regardless of type of risk, volume, or concentration, must be included in the CHP. The plan should define storage requirements, handling procedures (including requirements for personal protective equipment), location of OSHA-approved MSDS (and other pertinent references), and the medical procedures to be followed if contact or overexposure occurs. Monitoring of vapor levels is required initially and whenever there is reason to believe that safe levels are routinely exceeded. Indications for monitoring must be defined in the CHP. The CHP must specify the clinical signs and symptoms or the environmental conditions (such as a spill) that would indicate that overexposure has occurred. When such conditions exist, the CHP should describe

[1] 29 CFR 1910,1200
[2] 29 CFR 1910,1450

the medical attention that will be provided. There should be evidence that the plan is reviewed annually for its effectiveness. Good laboratory practice includes making the CHP part of new-employee orientation and continuing education programs.

Chemical carcinogens, reproductive toxins, and other severely toxic chemicals are special concerns. The laboratory must evaluate the carcinogenic and toxicity potential of chemicals in the laboratory. This includes any chemical for which OSHA has specific occupational regulations.[3] (Formaldehyde, ethylene oxide, benzidine, and benzene are examples in this group that are reasonably likely to be found in laboratories.) The regulations also apply to any chemical that is believed to be potentially carcinogenic. This includes any substance so identified by the National Toxicology Program or by the International Agency for Research on Cancer. The director or designee must have completed this exercise before the inspection, and a deficiency should be cited if there is no documentation that such an exercise has occurred.

Each laboratory must have a written plan to reduce or eliminate mercury. 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 various reagents.

Personal protective equipment (PPE) appropriate to each hazardous task must be provided and its use must be mandated where appropriate. Such items include face shields, aprons, and gloves constructed of materials appropriate to the type of chemical handled. Piped eyewash fountains or the equivalent should be present. Plumbed eyewash fountains must be checked weekly. It is a deficiency if this equipment is present but access to it is obstructed. Chemical fume hoods must be checked annually for proper function.

Formaldehyde vapor is the most likely air contaminant to exceed the regulatory threshold in the clinical laboratory. Details of current regulations on formaldehyde monitoring are described in the checklist. Warning signs must be posted where significant hazards exist.

Universal/Standard Precautions: A system of universal or standard precautions against the infectious hazards of blood and body fluids must exist. OSHA requires education of all employees whose work involves the potential for contact with such substances. Those whose work likely involves contact with body substances must use gloves and other appropriate personal protective equipment (gowns, masks, and eye protectors, etc.) in all situations during which exposure is likely to occur.

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 National Institute for Occupational Safety and Health (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.

The inspector should cite a deficiency if the use of gloves or any other item commonly associated with universal precautions is not part of the laboratory's practice. Cleaning and disinfecting of disposable gloves for reuse are prohibited. Gloves, aprons, or laboratory coats and protective eyewear must be provided and are required for those activities likely to result in contamination of skin or mucous membranes. Non-latex or powder-free latex gloves should be used to prevent hypersensitivity reactions to latex proteins. To prevent the transmission of potentially infectious agents, OSHA requires hand washing

[3] 29 CFR 1910,1001-1047

or antisepsis after glove removal. The Centers for Disease Control and Prevention (CDC) has published guidelines for hand hygiene. If hands are visibly dirty or contaminated with blood or proteinaceous material, the CDC recommends that the individuals 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.

Documented procedures detailing procurement, transportation, and handling of patient specimens (blood, body fluids, and 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 must be in place. If pneumatic tube systems are used for transporting specimens, the laboratory must have procedures to respond to a spill, including appropriate decontamination measures. There must be documented procedures for handling spills of blood and other body fluids.

Microbiological Hazards: The laboratory should have policies and procedures for assessing the occupational risk associated with exposure to infectious agents handled in the microbiology laboratory. The four biosafety levels for working with infectious agents are described in the CDC-National Institutes of Health (NIH) guideline *(Biosafety in Microbiological and Biomedical Laboratories,* U.S. Dept. of Health and Human Services, Fourth Edition, May 1999).[4] The laboratory must assess the biosafety level in which it operates and have policies and procedures appropriate to that level. Engineering and work practice controls appropriate to the biosafety level of the laboratory should be defined and implemented.

A functional biological safety cabinet (BSC) must be in use when culturing mycobacteria, fungi, and viruses. *Biosafety in Microbiological and Biomedical Laboratories*[4] has an extensive discussion of cabinet types and their requirements. The inspector must determine if the laboratory has the appropriate equipment in use and if the equipment functions as intended. Each BSC must be certified annually. The inspector should review the records to ensure that the annual inspection included filter checks, flow rate measurements, and tests for seam integrity.

Waste Disposal: The method for the disposal of all solid and liquid waste must be in compliance with applicable local, state, and federal regulations. There should be an ongoing program for hazardous waste minimization. The Environmental Protection Agency regulates the disposal of biohazardous waste such as specimen collection tubes, tissues, and bacteriologic cultures. In general, all such waste must be either incinerated or disinfected before burial in a sanitary landfill. All sharps, especially those contaminated with potentially infectious materials, must be properly discarded in puncture-resistant containers with tightly fitted lids.

The inspector should review the laboratory's documented policies and procedures for waste disposal and cite the laboratory if the manual lacks appropriate detail or omits important items. Technologists should be questioned regarding the segregation of wastes by hazard class at the point of generation to determine whether they understand the facility's policy. An inspector should visit the collection point at which wastes are collected for transportation to an off-site facility or for final disposition and try to determine the director's understanding of the final handling of all hazardous wastes.

Radioactive Hazards: Laboratories using radionuclides must manage them in a responsible manner. The Chemistry and Toxicology Checklist should be used to inspect laboratories that use radionuclides. There must be 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.). These policies and procedures should be developed in conjunction with the institutional radiation safety office and in compliance with

[4] HHS publication, 1993 stock #017-040-00523-7

any state regulations for the safe handling of tissues containing radionuclides. The policies and procedures should distinguish between low radioactivity specimens such as sentinel lymphadenectomy and implant devices with higher radiation levels.

Disaster Preparedness: The laboratory safety manual must have a section on "Internal and External Disaster Preparedness." A series of policies and procedures must be available to be followed in the event of a catastrophe such as fire, flood, electrical outage, or spill of hazardous volatiles (internal disaster), or a tornado, earthquake, or other mass-casualty situation (external disaster). The form that this portion of the safety manual takes is unique to each laboratory. There must be a comprehensive and workable documented evacuation plan for the laboratory. This plan must cover all employees, patients, and visitors and address the special needs of persons with disabilities. The inspector should cite a deficiency if it is believed that the laboratory's documented plans are inadequate.

Ergonomics: There should be a documented ergonomics plan. This plan may include training of employees about risk factors that cause musculoskeletal disorders, assessment activities to identify physical work activities or conditions of the job commonly associated with these difficulties, and recommendations for eliminating risk. Laboratory activity, workplace, and equipment (e.g., chairs, laboratory work stations, computer keyboards, and displays) should be designed to reduce the risks of ergonomic disorders and accidents.

Visit the CAP Web site Virtual Library of Audioconferences to hear the “Laboratory Safety” audioconference.

Anatomic Pathology (ANP)

Inspection of Anatomic Pathology is not limited to the contents of the Anatomic Pathology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Anatomic Pathology Checklist covers general anatomic pathology, surgical pathology, the histology laboratory, immunohistochemistry, immunofluorescence, fluorescence in-situ hybridization (FISH), autopsy pathology, and electron microscopy. The inspector is expected to evaluate all aspects of quality control and quality management in the various sections of anatomic pathology. The inspector will consider procedural and technical activities (process or quality control), issues related to the professional role of the pathologist (quality management), and an evaluation of the quality of the diagnostic report (features of both quality control and quality management). The inspector should spend at least several hours inspecting the anatomic pathology laboratory. The on-site inspection will require the inspector to review the reports and slides of at least 10 surgical pathology cases (preferably of various complexities and types), five autopsies, and example slides of all routine and special stains offered. Direct observation of technical procedures and careful review of quality management monitors are required elements of the inspection. Inspectors should be familiar with the CAP publication *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005* (formerly the *Quality Improvement Manual in Anatomic Pathology)*.

Because the sections of anatomic pathology ultimately deal with subjective, consultative medical opinion, the inspector should recognize that different laboratories vary in their design and implementation of overall quality management programs. It is important that the inspector not insist on "my way," but rather

make an effort to determine whether the programs and procedures in place achieve the fundamental goal: Providing the referring physician with an accurate, timely, and clinically relevant diagnostic report based upon the interpretation of optimal technical preparations.

Quality Management (QM) Program: The preamble to this part of the checklist designates the activities that must be included. The design of the program is the responsibility of the laboratory director. The laboratory must have a clearly defined, documented QM program that includes active monitoring of laboratory activities. Evaluation of the results of monitoring must be documented. Quality monitors or indicators may differ among laboratories. The QM program must ensure quality throughout the pre-analytic, analytic, and post-analytic phases of testing—including specimen identification, preservation, transportation, and processing—and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems and identifying opportunities for system improvement. The laboratory must document the corrective/preventive actions taken based on data from its QM program. While the type of program will vary according to the staff size and the volume and type of diagnostic material, the basic quality control/quality management principles of description, organization, systematic review, documentation, communication, and turnaround time must apply. Technical and procedural quality control are integral components of comprehensive quality management and should be included. Results of QM monitoring surveillance should be shared with the responsible pathologist(s).

Proficiency Testing: The laboratory should participate in interlaboratory comparison, self-assessment, and performance improvement programs. There must be records of intra- and extra-departmental consultation, as appropriate.

Quality Control: These questions address issues concerned with collection and accessioning of specimens, the surgical specimen examination area, and procedures related to surgical specimen examination. Although not solely a quality control issue, surgical consultation (rapid diagnosis or frozen section) is addressed in this portion of the checklist. Review of the quality and turnaround time of surgical pathology reports is considered in this part. Questions also address the need for clear and concise gross descriptions that contain adequate information about the lesions present. The final diagnosis should correlate with the descriptions, provide sufficient information to contribute to patient management, and be available in a timely fashion. The laboratory should have a mechanism to correlate the results of specialized studies (e.g., electron microscopy, immunohistochemistry, nucleic acid probes, and cytogenetics) with the morphologic diagnosis, and to reconcile **potentially conflicting data, when appropriate.**

Histology: Quality control items include evaluation of procedure manuals, histologic preparations, special stains, instruments, and equipment. Questions pertaining to immunohistochemistry are included in this section of the ANP Checklist.

There are several key areas to focus upon during the inspection of immunohistochemistry (IHC), including the oversight functions of the responsible pathologist, annual review of procedure manuals, and participation in a peer education program (e.g., CAP Educational Anatomic Pathology Program Survey MK Immunohistochemistry). The inspector should ensure that there is documentation of corrective action and pathologist review of quality control problems, as well as validation of new antibody lots and of procedures that were implemented since the last on-site inspection.

A comprehensive discussion of positive and negative controls in immunohistochemistry has recently been added to the checklist (see ANP.22550 and ANP.22570). Internal positive controls are acceptable (for

instance, staining of vascular smooth muscle by smooth muscle actin), but the procedure manual must indicate the manner in which such controls are used for each antibody affected. Negative controls should include both a reagent control (primary antibody omitted) and a tissue control (absence of staining in tissues that lack the antigen).

If the laboratory is engaged in IHC for predictive markers such as HER2, the report should include information on specimen processing, the antibody clone, and the scoring method used. There should be periodic comparison of laboratory performance with published benchmarks and an evaluation of interobserver variability.

If the laboratory performs HER2 testing, it should have a documented plan to implement the new ASCO/CAP Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer; these may be found at http://www.cap.org and may be periodically revised. An acceptable implementation plan consists of appropriate development steps that may include: (1) review of the guideline document, (2) written evaluation of the laboratory's current relevant policies and procedures, (3) gap analysis of existing policies/procedures, (4) written schedule to address identified gaps, and (5) evidence of implementation of changes. Compliance with the guidelines will be required as of December 31, 2007.

The inspector should assess the quality of the immunostains by direct review of immunostained slides. Sample pathology reports representative of the reporting format used for IHC immunostains should be reviewed along with the slides.

The inspector should meet with the supervisor and, if needed, with the pathologist serving as medical director, to ascertain the regulatory classification types of reagents used in the laboratory. Primary antibodies used for clinical immunohistochemistry testing are classified in one of four regulatory categories:

Class I ASR
Class I for In Vitro Diagnostic Use (INVDU)
Class II for INVDU
Class III for INVDU

Most antibodies used for clinical IHC are Class I ASR or Class I for INVDU. The checklist contains an extensive discussion regarding the use and reporting of ASRs (see ANP.12425).

Regardless of the regulatory class of reagent, the best approach is to perform in-house validation and documentation, even for Class II and III reagents. It is well recognized that IHC analytical testing represents a key but small part of a total analytical system that includes a variety of complex pre- and post-analytical controls.

Further information can be obtained at the FDA Web site at www.fda.gov/cdrh/ode/immuno.html or www.fda.gov/cdrh/oivd/index.html.

Safety: Safety questions emphasize the adequacy of ventilation in areas of specimen handling and processing, and the handling of infectious tissues and other contaminated materials, including special precautions related to Creutzfeldt-Jakob disease. The inspector should review relevant questions from the Safety section of the Laboratory General Checklist to ensure that the Anatomic Pathology section is in compliance.

The laboratory must perform an initial formaldehyde monitoring procedure in all areas where this reagent is used. Further periodic formaldehyde monitoring is mandated if results of the initial monitoring equal or exceed 0.5 ppm (eight-hour time-weighted exposure, the "action level") or 2.0 ppm (15-minute exposure, STEL). The laboratory may discontinue periodic formaldehyde monitoring if results from two consecutive sampling periods taken at least seven days apart show that employee exposure is below the action level and the short-term exposure limit, and (1) no change has occurred in production, equipment, process, or personnel or control measures that may result in new or additional exposure to formaldehyde, and (2) there have been no reports of conditions that may be associated with formaldehyde exposure.

Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene.

Results Reporting: The inspector should review 15-20 completed reports for adequacy of specimen descriptions and diagnoses, inclusion of sufficient information for grading and staging of neoplasms, and correlation of special studies (e.g., immunohistochemistry, electron microscopy) with the final diagnosis. Reports should be signed (either electronic or physical signature) by the responsible pathologist, and the laboratory should have a procedure that ensures and documents that the responsible pathologist has reviewed and approved the completed report before its release. There should be a policy regarding the timely communication and documentation of significant or unexpected diagnostic findings.

Autopsy Pathology: Items emphasized include timely reporting of both preliminary and final diagnostic findings, and policies regarding proper conduct of autopsies on patients with known or suspected infectious diseases. In addition, the important role that the autopsy plays in quality assurance must be addressed, including both the quality of autopsy performance itself and the manner in which it may enhance the quality of patient care.

Practical suggestions for implementing and documenting these and other measures can be found in the CAP *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005.*

Electron Microscopy: The initial part of this section is concerned with quality control issues such as procedure manuals, specimen collection, specimen preparation, instruments and equipment, reports, and records. This is followed by a review of the physical facilities and safety items that pertain specifically to the electron microscopy service.

Physical Facility: Special attention should be given to the suitability of space and environment for microscopic study.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Inspecting the Surgical Pathology Laboratory" audioconference.

Clinical Chemistry and Toxicology

Inspection of Clinical Chemistry is not limited to the contents of the Clinical Chemistry and Toxicology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Chemistry and Toxicology Checklist (CHM) addresses:

1. Basic chemistry procedures, typically performed on automated and semi-automated instruments, including blood gas analysis and oximetry
2. Toxicology testing, including all screening and/or confirmatory testing for drugs of abuse, legal alcohol analysis and other toxicology tests, regardless of methodology
3. Therapeutic drug monitoring (TDM) regardless of instrument or method
4. Specialized tests such as prenatal screening for fetal anomalies; cystic fibrosis screening; immunoassays (including testing for hepatitis and other viral markers); assays performed by flame photometry, atomic absorption, chromatography and mass spectroscopy, and electrophoresis

If **radioimmunoassay** is performed, the inspector must review the radiation safety manual and personnel records for documentation of radiation exposure. The inspector should ask to see the facility's radiation license. The laboratory may be regulated under a general license[5] if the facility uses only small amounts of radioactive materials. This is commonly the case when commercially prepared kits are used. The amounts per kit must be documented. Alternatively, the facility may hold a specific license granted to it by the Nuclear Regulatory Commission. A specific license has all the elements of a general license as well as additional items that have been tailored to the requirements of that facility. The checklist includes several questions that commonly apply to facilities with a specific license; however, the inspector should inspect such a facility according to the *actual requirements* listed in that specific license.

Laboratories performing only **blood gas testing** now use the CHM Chemistry and Toxicology Checklist, but will receive questions related only to blood gas and oximetry testing, as applicable. The Blood Gas Laboratory Checklist was eliminated as a separate checklist in 2003. Blood gas control testing requirements have changed to at least one level for pH, pCO2, and pO2 every eight hours of patient testing, with a low and high level required each day of patient testing.

Some laboratories may choose to perform certain tests exclusively for **legal** purposes (e.g., alcohol for traffic law enforcement, and criminal justice and medical examiner systems). In this case, the performance of legal testing must meet forensic, not clinical laboratory, standards. These forensic standards include the requirements for chain-of-custody protocols for specimens and aliquots, specimen seals, increased specimen and record security, appropriate confirmation testing, and a certifying review process.

Certain clinical tests have a higher potential for being involved in a legal proceeding, such as blood alcohol tests for motor vehicle accident patients and drugs of abuse tests for patients undergoing drug treatment or neonates suspected of drug exposure in utero. Therefore, a laboratory may choose to conduct these clinical tests using procedures and policies that meet both forensic and clinical laboratory standards. It is not a CAP requirement, however, to conduct any clinical testing using the standards of legal testing; it is an administrative decision to do so. Toxicology testing for diagnosis, treatment, or other clinical purposes must meet only clinical laboratory practice standards.

Questions that relate specifically to legal or "forensic" toxicology testing requirements are in the "Legal Testing" section of the Chemistry and Toxicology Checklist. The questions address chain-of-custody, data review, reporting, and security. The inspector must use the Chemistry and Toxicology Checklist to cover positive screening results that are released as unconfirmed per client request, even if the laboratory

[5] 10 CFR31.11

is enrolled in the CAP Forensic Drug Testing (FDT) accreditation program. The inspector should pay particular attention to chain-of-custody documents, and restriction of access to specimens and forensic data in the laboratory computer system, as well as establishment of defined cutoffs and whether or not QC adequately challenges these cutoffs.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Inspecting the Toxicology Laboratory" audioconference.

The chemistry laboratory usually is the largest department in a full-service laboratory, and its test menu usually is extensive. Time does not permit a detailed review of every procedure, of calibration of every pipette and thermometer, or an extensive inspection of every quality control record. The emphasis should be selective, focusing on the areas of both highest and lowest volume, as well as on areas where test results most impact patient care (e.g., hCG, HIV, glucose), and on any apparent problem areas. It usually is more instructive to review the records for 10 tests comprehensively than to review the records for 50 tests superficially.

The Chemistry and Toxicology Checklist addresses laboratory equipment such as pipettes, glassware, thermometers, centrifuges, analytical balances, spectrophotometers, and other basic analytic systems. See page 35 in this manual in the area "Inspecting the Laboratory Sections, Requirements Common to all Laboratory Sections, Instruments and Equipment," for a more detailed discussion of equipment requirements. Equipment or instruments used for primary analysis of patient samples should be thoroughly examined. When analytical systems are maintained for backup purposes and are infrequently utilized, then evaluation should be directed to system maintenance and the adequacy of correlation between analyzers.

Calibration, calibration verification, and analytical measurement range (AMR): Verification records should be examined closely to ensure that the analytical system stability meets the claims of the instrument/reagent manufacturer. Calibration should be performed according to manufacturer instructions. Calibration or calibration verification must be performed every six months. If excessive time has elapsed between calibrations, a separate calibration verification process is required. Analytical measurement range verification must be performed at a minimum of every six months with three concentrations of material that span the low, mid, and high portions of the AMR. AMR verification is not required if the calibration process utilizes at least three calibrators that span the AMR and if calibration is performed more frequently than every six months.

The **clinically reportable range** (CRR) is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct AMR. The establishment of the CRR is a medical judgment made by the laboratory director and is based, in part, on the assay technology. Once established, the CRR does not need to be re-evaluated unless the methodology changes for the analyte. Dilution protocols and diluents (or concentration protocols) should be specified for all methods for which the CRR is outside the AMR. The procedure manual must include the protocol for dilution or concentration, any diluents or other components used in the process, and the formula for calculation of the final reportable result. If there is a limit to the amount of dilution or concentration that is appropriate for a method, the procedure must state the limit and specify how to report results that exceed the CRR.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Calibration, Calibration Verification, and Analytical Measurement Range" audioconference.

The laboratory must be able to demonstrate ongoing system accuracy and stability. This is particularly important if the laboratory has elected infrequent quality control for certain systems. Appropriate multi-level control specimens must be used at least daily on days when patient specimens are tested.

The laboratory must have documented procedures for all required maintenance, with frequency and schedule noted. There must be evidence and results of all required maintenance.

***Waived Test Requirements**:* Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements section of this accreditation manual for specific details.

Cytogenetics (CYG)

Inspection of Cytogenetics is not limited to the contents of the Cytogenetics Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Cytogenetics Checklist is used for the inspection of laboratories performing cytogenetic and fluorescence in situ hybridization (FISH) studies of amniotic fluid, bone marrow, chorionic villi, chromosome breakage, blood lymphocytes, solid tumors, and non-neoplastic tissue cultures.

Inspector Requirements: Cytogenetics inspectors should be qualified pathologists, cytogeneticists, or cytogenetic technologists who are actively involved with or have extensive experience in the practice of cytogenetics, and are knowledgeable about current CAP checklist and corresponding CLIA ’88 requirements. A list of cytogenetics specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP Inspector Database Specialist at 800-323-4040, extension 7380, for the names of additional qualified inspectors.

Inspection Process:

- Observe the processes of specimen accessioning, culture, harvest, slide preparation, microscopy, and reporting, mailing, and filing. Check for safe work practices.
- Select at least 10 recent representative studies and evaluate the laboratory’s practice with regard to test requests, specimen processing, records, and report standards.
- Meet with the laboratory director and clarify any discrepancies noted between written procedures and observed laboratory practices. Discuss any deficiencies or recommendations.

Procedures and Test Systems: All cultures should be set up in duplicate or established independently. Duplicate amniotic fluid and chorionic villus cultures must be harvested independently. Request to review the records of failed cultures and sub-optimal analyses. Look for evidence that the reasons for culture failures have been investigated and actions taken for improvement opportunities. For prenatal testing, there should be an attempt to follow-up each abnormal amniocentesis result at the time of parturition or termination.

Cells Counted and Analyzed: The minimum number of cells to be studied is a function of sample source, culture technique, and other factors. Specific requirements are addressed in various checklist items.

Band Resolution: The laboratory should use a defined and reproducible method for identifying band levels. Band resolution is expected at 550 bands for appropriate blood samples and 400 bands as the minimum acceptable standard for all other cases. Lower resolution should be exceptional and explainable.

FISH: Review a sampling of FISH cases and controls, evaluating signal, background, and morphology. There should be documentation of validation of commercially available and home-brew probes. If FISH testing is performed using Class I analyte-specific reagents (ASRs) obtained or purchased from an outside vendor, the patient report must include the disclaimer statement required by the FDA.

HER2: If the laboratory performs HER2 testing, it should have a documented plan to implement the new ASCO/CAP Guideline recommendations for HER2 Testing in Breast Cancer; these may be found at http://www.cap.org/ and may be periodically revised. An acceptable implementation plan consists of appropriate development steps that may include: (1) review of the guideline document, (2) written evaluation of the laboratory's current relevant policies and procedures, (3) gap analysis of existing policies/procedures, (4) written schedule to address identified gaps, and (5) evidence of implementation of changes. Compliance with the guidelines will be required as of December 31, 2007.

Reports:

- The Cytogenetics report must include the name and address of the testing laboratory, patient name, unique identifying number, patient date of birth, physician name, specimen source, date of specimen receipt, date of report, clinical indication for the test, cells counted, analyzed, and karyotyped, band resolution and methods, and comments on specimen adequacy, if indicated.
- Review several normal and abnormal cases and investigate how the laboratory handles a sample received without clinical information or diagnosis.
- Photographs and other records must substantiate the final interpretation of each case.
- Investigate how abnormal results are communicated to referring physicians.
- The current edition (1995) of the *International System for Human Cytogenetic Nomenclature (ISCN)* must be used correctly in the final report for conventional cytogenetics.
- FISH result interpretation should be made with reference to internal, historical, or concurrent controls.
- Errors occurring in the final report (such as typographical sex-designation errors) must be thoroughly investigated and the results of the investigation documented.
- Preliminary reports, especially verbal or telephone reports, must be documented on the final report.
- The final report should contain recommendations for genetic counseling and/or additional studies of the patient and/or family members, when appropriate.
- Report turnaround times: 90% of reports must be available as follows:

• Amniotic fluid and chorionic villi analyses	Final:	14 days
• Non-neoplastic blood	Final:	28 days
• Stat chromosomal analysis	Preliminary:	3 calendar days
• Stat chromosomal analysis	Final:	7 days
• Non-neoplastic, fibroblast:	Final:	6 weeks
• Neoplastic blood and bone marrow	Final:	21 days

Visit the CAP Web site to hear the "Inspecting the Cytogenetics Laboratory" audioconference.

Cytopathology (CYP)

Inspection of Cytopathology is not limited to the contents of the Cytopathology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The inspector should be a pathologist and/or supervisor-qualified cytotechnologist actively involved or experienced in the current practice of cytopathology and conversant with contemporary quality

management practices and the CLIA ’88 regulations pertinent to cytopathology. In addition to the checklist, it is helpful for the inspector to review the CAP *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005 (*formerly the *Quality Improvement Manual in Anatomic Pathology)* and the CLIA ’88 regulations. The inspector should plan to spend several hours inspecting the cytopathology section regardless of case volume. The on-site inspection will require documented review of case (slide) material, direct observation of technical procedures, and careful review of quality management practices. The inspection process should confirm compliance with each checklist item pertinent to the laboratory.

The Cytopathology Checklist (CYP) was reorganized to streamline the inspection process by creating specific sections for general cytopathology, gynecologic cytopathology, and non-gynecologic cytopathology.

Personnel and Screening: The inspector must review the qualifications of the pathologist director (technical supervisor), general supervisor, and cytotechnologist(s), and assess documentation that shows the performance of their respective responsibilities, as outlined in the checklist. The cytopathologist may serve as the general supervisor. The qualifications for general supervisor can be the same as that of laboratory director (technical supervisor). Alternatively, the general supervisor can be qualified as a cytotechnologist under 42CFR493.1483, with at least three years of full-time experience as a cytotechnologist within the preceding 10 years. The general supervisor, as designated by the laboratory director, is responsible for day-to-day supervision and oversight of the laboratory operation and personnel who perform testing and reporting of test results. This individual must also:

1. Be accessible to provide consultation to resolve technical problems.
2. Document the slide interpretation results of each case he/she examined or reviewed.
3. For each 24-hour period, document the total number of slides he/she screened or rescreened, as well as ensure documentation of the total number of slides evaluated by others.
4. Document the number of hours he/she spent examining slides in each 24-hour period.

The importance of the screening process should be considered. Sufficient qualified personnel and space should be available to handle the case volume and variety. The inspector should evaluate whether the facility provides adequate space and a suitable environment for screening. Although CLIA ’88 establishes maximum workload limits, the laboratory director is obligated to establish individual workloads, as indicated in the checklist. The inspector should carefully evaluate these factors, together with applicable quality control and quality management data, when judging the adequacy of cytopathology laboratory staffing. These total limits apply regardless of the number of laboratories in which an individual works on a given day. The inspector should review the documented workload policy to ensure the workload is reassessed at least every six months for individuals who screen slides, and that the number of slides screened by each individual is documented daily.

At a minimum, performance must be evaluated using the results of the following: (1) rescreening of 10% of the cases interpreted to be negative; and (2) comparison of the cytotechnologist’s interpretation with the final diagnosis of abnormal cases. The laboratory may use additional methods of evaluating performance such as retrospective reviews, comparison of individual statistics with overall lab statistics, and competency assessment. For primary screening of gynecologic liquid-based preparations, each slide must be counted as a single slide for the purpose of workload recording. For primary screening of non-gynecologic liquid-based slide preparations, each slide may be counted as one-half slide for the purpose of workload recording provided that cells are evenly dispersed over one-half or less of the total available slide area. Workload calculations may vary with the use of automated screening instruments. Laboratories

should follow the instrument manufacturer's workload calculation instructions and must ensure that CLIA '88 requirements are fulfilled.

Proficiency Testing: For laboratories subject to CLIA '88 regulations, all individuals engaged in the examination of gynecologic preparations must participate in a CMS-approved PT program in gynecologic cytopathology. If a laboratory has a CLIA license to perform gynecological cytology, but the laboratory personnel are testing or have tested at another CLIA location, the laboratory must obtain a site enrollment to be in compliance. Laboratories must maintain documentation of PT performance for at least two years. Documentation must be kept for each individual participating in annual PT, including identification of those who are retested; documentation of remedial training; records of imposition of limitations on slide examination; and records of re-examination of slides, as required by CLIA '88.

For laboratories not subject to CLIA '88, educational opportunities should also be appraised. If the laboratory examines gynecologic specimens, it should be enrolled in the CAP Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP) or another educational program in gynecologic cytopathology. Other internal or external programs may be utilized to meet further educational and personnel evaluation needs appropriate to the laboratory's scope of practice. Good laboratory practice dictates that a laboratory that examines non-gynecologic specimens should enroll in the CAP Interlaboratory Comparison Program in Non-Gynecologic Cytopathology (NGC) or another program to evaluate employee performance.

Procedure Manual: The inspector should evaluate the laboratory's standard operating procedures and ensure that all significant information and instructions are included, and then verify that actual practice matches the contents of the procedure manuals.

The inspector should observe procedures for specimen accessioning and processing, staining, screening, hierarchic review, preparation of reports, and storage and retrieval of slides. Each of these activities should correspond to the laboratory's documented procedures. During specimen accessioning and processing, the adequacy of safety measures should be evaluated.

Criteria should be documented and implemented for rejection of specimens and for classification of specimens as unsatisfactory, and procedures should address notification of the submitting physician in these cases. Measures for prevention of cross-contamination of specimens should be included in processing/staining procedures. Case management procedures should cover the screening process and specify criteria for rescreening and pathologist review.

Reports: Documented policies and procedures must be in place for issuing reports, including amended reports when indicated, for ensuring communication of findings to the submitting physician (especially critical and complex findings), and retention and retrieval of reports and slides. Reports must include a concise descriptive diagnosis, either in a format similar to a histopathology report or in standard descriptive terminology that includes a general categorization and descriptive diagnosis. The use of diagnostic "classes" is not recommended, as it does not reflect current understanding of neoplasia, has no comparable equivalent in diagnostic histopathology terminology, and does not provide for diagnosis of non-neoplastic conditions.

The laboratory should have a policy to educate providers of cervicovaginal specimens that the Pap test is a screening test for cervical cancer with an inherent false-negative rate. The preferred mechanism is an educational note on all Pap test reports that are negative (within normal limits) or display benign cellular changes. Other mechanisms include sending periodic educational information to providers.

A simple diagnosis of "Negative" is not an adequate descriptive diagnosis. However, a diagnosis such as, "Negative for malignancy" or “No malignant cells identified" is acceptable for non-gynecologic exfoliative cytology specimens (i.e., urine, fluids, washings and brushings). When appropriate (particularly for fine needle aspiration samples of mass lesions), a statement regarding the adequacy of the specimen should be included, with a description of the limitations of the specimen when a specific diagnosis cannot be made.

The cytopathology report must clearly indicate the name of the pathologist who has reviewed the slides, when applicable. The records must indicate those who have reviewed the cytology slides. Cytotechnologists should be identifiable by name, initials, or other identifier in laboratory records. The reviewing pathologist’s name must be distinct from any other pathologists’ names (e.g., the laboratory director) on the report. No pathologist or cytotechnologist reviewer’s signature or initials may be present unless the individual personally examined the slides from the case, including those cases released through automated screening instruments.

When applicable, cytopathology reports must be reviewed and signed by the pathologist. For gynecologic cases reviewed by a pathologist, and for all non-gynecologic cases, the laboratory must ensure and document that the reviewing pathologist has reviewed and approved the completed report before release. In the occasional situation when the diagnosing pathologist is not available for timely review and approval of the completed report, the laboratory may have a policy and procedure for review and approval of that report by another pathologist. In that circumstance, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performs final verification must appear on the report or be retrievable within the laboratory’s records.
Records must be retained in accordance with the requirements listed in the Laboratory General checklist. In addition, cytopathology reports must be retained for a minimum of 10 years.

Cytopathology reports may be retained in either paper or electronic format. Images of paper reports, such as microfiche or PDF files, are acceptable. If retained in electronic format alone, however, the electronic reports must include a secure electronic signature. Since a five-year "look-back" period is required when there is a newly identified high-grade abnormality in cervical cytopathology, non-computerized laboratories may wish to retain gynecologic cytopathology accession records for five years.

On-site Case Review: On-site review of actual case (slide) material and corresponding reports is an important element of the inspection process. This is NOT a comprehensive rescreening of slides or an evaluation of competency, but rather an effort to facilitate the inspector's evaluation of the laboratory's overall procedures. Although the case selection method may vary among inspectors, the following suggestions have been offered by members of the CAP Cytopathology Resource Committee and endorsed by the Commission on Laboratory Accreditation:

> Cases should be selected from a variety of diagnostic categories. Time should be allotted to review at least 10-15 cases. The Inspector should choose several randomly selected negatives as well as cases from unsatisfactory, reactive, low-grade and high-grade intraepithelial lesions, atypical squamous cells (ASC), and positive for malignancy categories, as well as cases from non-gynecologic sources. Cases should be selected by the laboratory pathologist and/or cytopathology supervisor in a random manner that may be defined by the inspecting Team Leader (e.g., the first 1-3 negative and abnormal cases in each specimen category from a certain date or week). The following are core elements of the on-site review:

1. Slides should be evaluated for quality of technical preparation as well as specimen adequacy.
2. Significant cells should have been identified.
3. Slides should be compared with the diagnostic report for completeness and clarity of diagnostic terminology.
4. The information provided with the requisition and included in the diagnostic report should be complete and appropriate.

The specimen type and diagnostic categories of the actual cases reviewed (not the case ID number) should be recorded in the Inspector's Summation Report. **The inspector must complete the on-site microscopic review chart in Part B of the ISR** by recording the number of cases reviewed (not the pathology numbers) in each category. If, during the on-site review, there is believed to be a significant diagnostic discrepancy, this should be discussed by the pathologist team leader with the laboratory director.

Interpretations may be considered discrepant if they are not in the same series of the Diagnostic Menu of the CAP PAP Program (e.g., "100 series" versus "200 series"), or comparable major diagnostic classifications in an approved non-CAP program. Cases considered to be "ASC/AGC" (either by the inspector or inspectee) should not be included in the analysis to determine significant discrepancies because of the current lack of interlaboratory reproducibility of these interpretations.

Instrumentation: With the increasing use of automated instruments in the cytology laboratory, it is important that inspectors review the implementation, training, and procedures for these instruments. Before implementing new gynecologic liquid-based methods and instruments, automated preparations, and automated screening instruments, the laboratory must validate and document the functioning of the instrument in its own specific laboratory environment, including the capability of the instrument to replace existing procedure(s), if applicable. If the manufacturer does not provide validation and instrument monitoring recommendations, the laboratory must document the specific validation procedure used.

There must be documentation of appropriate technical and interpretive training for each instrument used. Instrument performance should be routinely verified and monitored, with documented corrective actions and procedures for handling cases during instrument failure. Ongoing monitoring of instrument function and maintenance records on all devices must be documented. Monitoring of device operation must be in accordance with manufacturers' instructions. If the manufacturer does not provide monitoring recommendations, the laboratory must document the specific monitoring procedures used. Limits of acceptable variation must be defined in laboratory procedures.

A sample of slides from slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, should be routinely reviewed microscopically for technical acceptability.

Safety: Safety questions emphasize the adequacy of ventilation in areas of specimen handling and processing and the handling of infectious tissues and other contaminated materials. The inspector should review relevant questions from the Safety section of the Laboratory General Checklist to assure that the cytopathology laboratory is in compliance.

Quality Management: The facility's QM program should address the validation of both normal and abnormal diagnoses and the assessment of laboratory and personnel performance. Quality measures for abnormal findings should include such activities as peer and hierarchic review, correlation of cytologic

findings with histologic and clinical findings, documented evaluation of significant discrepancies, and appropriate use of intradepartmental and extradepartmental consultation.

Evaluation of the quality of negative findings is more difficult, but is very important in reducing the likelihood of a false-negative report. Routine evaluation of specimen adequacy is essential to ensure that diagnostic interpretations are not reported on unsatisfactory specimens. Among other useful techniques are retrospective review of previous material whenever a new significant abnormality is identified and prospective rescreening of negative cases. An individual qualified to be a cytology supervisor must prospectively rescreen at least 10% of gynecologic cases screened as negative by a cytotechnologist. Rescreened slides must include both randomly selected and high-risk cases. Rescreening of random negative specimens enables monitoring of false-negative fractions, whereas rescreening of specimens from "high-risk" patients is more likely to identify abnormalities. The documented rescreening program must include negative gynecological smears received within five years of a new high-grade intraepithelial lesion or cancer diagnosis, if applicable.

The inspector should assess the procedures for rescreening and hierarchic review, including criteria for case selection (e.g., identification of "high risk" and retrospective review specimens) and provision of feedback to the original screener. The statistical records for gynecologic and nongynecologic specimens should be reviewed; benchmark data from CAP interlaboratory comparison programs are useful in evaluating the laboratory's statistical results.

All quality surveillance activities should be documented, with evidence of review and evaluation. Findings should be shared with the responsible pathologists and cytotechnologists. Results should be incorporated into revisions of policies, procedures, and personnel assignments and workload.

Practical suggestions for implementing and documenting these and other measures can be found in the CAP *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005.*

Visit the CAP Web site to hear the audioconferences "Is Your Inspection Team Prepared for a Cytology Inspection?" and “Inspecting Cytopathology.”

Flow Cytometry (FLO)

Inspection of Flow Cytometry is not limited to the contents of the Flow Cytometry Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

A qualified flow cytometry inspector should inspect laboratories that provide flow cytometry services. A list of flow cytometry specialty inspectors is provided to the inspection team leader in the Inspector’s Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP Inspector Database Specialist at 800-323-4040, extension 7380, for the names of additional qualified inspectors.

This checklist includes DNA content and cell cycle analysis. The laboratory must document the optical alignment and instrument sensitivity, and run fluorescent beads daily. All reagents must be used within the manufacturer’s stated expiration date.

Hematology and Coagulation (HEM)

Inspection of Hematology and Coagulation is not limited to the contents of the Hematology and Coagulation Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

Automated Blood Cell Counting: The laboratory must have a documented, detailed procedure for calibration of automated complete blood count (CBC) instruments, including indications from the quality control system of when recalibration is needed. Calibration techniques may include the use of stabilized commercial preparations or fresh whole blood specimens. If non-adjustable, precalibrated instruments are used, calibration must be verified with appropriate control materials.

Daily quality control procedures may include any combination of the following three approaches. Tolerance limits must be defined.

1. **Processing of stabilized commercial control materials:** Two different concentrations (preferably normal and high) are required for each 24 hours of patient testing. The laboratory should plot standard Levy -Jennings graphs with control limits and apply at least some Westgard multi-rule criteria for determining if results are analytically acceptable. It is important for the laboratory to determine its own in-house QC acceptance ranges based on its instrument's between-day imprecision rather than just utilizing the package insert values for the expected recovery range. There is no requirement for three control levels, and the use of dilute low particle concentration controls is discouraged.
2. **Retained patient specimens:** While traditionally applied to CBC instruments, this approach is only valid if there are defined limits of numeric agreement for each parameter between successive samplings.
3. **Moving average algorithm for erythrocyte indices and other parameters:** The laboratory should set limits that are sensitive to significant alterations in calibration status, yet insensitive to minor fluctuations in patient population values.

Fluids used with CBC instruments must be periodically checked for contamination. Suggested checks include pH, osmolality, and instrument background counts. Since nucleated erythrocytes and blood megakaryocytes may have an additive effect on the instrument leukocyte count, appropriate count correction procedures must be present for these constituents. There also must be protocols for common interferences that may affect the accuracy of CBC data, such as lipemia, in-vitro hemolysis, microclots, cold agglutinins, and rouleaux. Patient results that exceed laboratory defined reportable limits must be verified (e.g., cytopenic samples should be checked against hemocytometry or blood film estimates) prior to reporting.

Automated Differential Counters: Such instruments must be carefully evaluated against previous patient-testing methods before being placed in service. Quality control options include periodic comparisons with manual differentials or processing of commercial control materials with at least two different classes of leukocytes or WBC surrogates. The laboratory must have criteria for checking and reviewing leukocyte differential counter data, histograms, and/or blood smears, which have clinically important results flagged by the automated counter.

Manual Blood Films: There must be documented criteria for review of blood films with specified abnormalities by the pathologist, supervisor, or other technologist qualified in hematomorphology. The laboratory should have a system that ensures that all personnel report microscopic morphology in a similar fashion. Suggested methods to accomplish this include:

- Circulation of blood films with defined leukocyte differential distributions and specific qualitative abnormalities of each class of cells, and/or
- Multi-headed microscopy, and/or
- Use of blood or bone marrow photomicrographs with referee and consensus identifications, such as those from previous CAP Surveys.

Automated Reticulocytes: The laboratory should have precision data for its automated method, based on analysis of commercial controls or comparison with manual methods. Documented criteria should be present for identifying samples that may give erroneous results due to interferences (e.g., Howell-Jolly bodies, nucleated RBC, basophilic stippling, macrothrombocytes). For flow cytometry systems not using commercial kits approved by the FDA, there should be evidence of evaluation of the strength and stability of the fluorescent dye binding to RNA or DNA-RNA.

Manual Reticulocytes: To reduce the imprecision of microscopic enumeration, the reported reticulocyte concentration must be based on a minimum sample size of 1,000 red cells. When using a Miller disc a minimum of 112 cells must be counted. The fields from which the count is taken must contain at least 1,000 red cells.

Bone Marrow Preparations: The inspector must review bone marrow slides (routine and cytochemical stains) to assess technical adequacy. If fixed tissue sections and aspirates are independently evaluated by different sections of the laboratory, there must be a mechanism to compare data and interpretations before reports are released by pathologists or qualified hematologists.

Abnormal Hemoglobin Detection: If the laboratory uses alkaline cellulose acetate or isoelectric focusing as a separatory technique, all abnormal bands must be verified by solubility testing, acid agar electrophoresis, and/or HPLC, as appropriate. In the absence of a primary screening method, solubility ("sickle") testing alone is not sufficient for detecting or confirming the presence of sickling hemoglobins, and a recommendation for further confirmatory testing must be made.

Body Fluids: The procedure manual must address handling of partially clotted specimens, cell clumps, or debris noted during hemocytometry or automated counting. For instrument counts, the laboratory should have documentation of linearity studies and defined limits beyond which instrument counts are not reliable. Differentials should always be performed on stained preparations, and use of the cytocentrifuge is strongly recommended. As with blood film morphology, there should be a system to ensure consistency of morphologic classification when multiple personnel are responsible for smear examination. A pathologist or other qualified physician must review body fluid preparations that contain suspected malignant cells.

Semen Analysis: This section covers basic semen testing. In addition to the checklist items addressing body fluid cell counts, there is an emphasis on issues of specimen collection, motility assessment, and stained morphology classification. More specialized requirements are found in the Reproductive Laboratory Checklist, which is used only for laboratories that participate in the Reproductive Laboratory Accreditation Program.

Coagulation Tests: Laboratories serving acute care hospitals must be able to perform a sufficient variety of coagulation tests to evaluate common coagulation disorders. Such tests typically include platelet concentration, prothrombin time, activated partial thromboplastin time, fibrinogen assay, fibrin(ogen) degradation products or D-dimer, and platelet function tests such as bleeding time or whole blood in vitro platelet function.

All coagulation specimens should be collected into 3.2% buffered sodium citrate, and there should be documented guidelines for rejection of under- or overfilled collection tubes.

Patient results should be reported with the accompanying reference ranges. Appropriate controls (at least two levels) must be performed for all procedures for each eight hours of patient testing.

For prothrombin time (PT), the laboratory must have documentation that the International Sensitivity Index (ISI) is appropriate to the particular PT reagent and instrumentation used. The ISI value may change with each new lot of PT reagent. The International Normalized Ratio(s) (INR) values are often used to monitor patient therapy with oral anticoagulant medications. It is critical to calculate and report appropriate INR values, which must be appropriately adjusted for every new lot of PT reagent, changes in types of reagent, or changes in instrumentation. The appropriate mean of the PT reference interval must be used in the INR calculation. Patient reports should be checked at least once per year for correct INR calculations, patient values, and reference intervals.

With improvements in the precision of semi-automated and automated coagulation instruments as well as more uniform commercial reagents, single test determinations are acceptable if appropriate quality standards are met. Single test results should be statistically indistinguishable from duplicate test results.

Plasma-mixing studies (i.e., mixing patient plasma with normal plasma) may be performed to distinguish whether a factor deficiency or an inhibitor causes an abnormal coagulation screening test result (PT or aPTT). When mixing studies are performed, the normality of the “normal” plasma must be verified. In general, pooled plasmas prepared in the laboratory or commercial products are acceptable.

The laboratory should have a procedure to detect heparin or other antithrombotic drugs that inhibit coagulation in patient samples. Platelet aggregation studies should be performed at 37 degrees Celsius, and blood specimens for initial platelet function studies and platelet aggregation must be handled at room temperature before testing.

If factor assays are performed, the inspector should examine sample assay data to determine that appropriate calibration points and two dilutions of patient plasma are routinely used.

Waived Test Requirements*:* Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 35).

Visit the CAP Web site to hear the “Inspecting the Hematology Laboratory” audioconference.

Histocompatibility (HSC)

Inspection of Histocompatibility is not limited to the contents of the Histocompatibility Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See

the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Histocompatibility Checklist is for laboratories performing HLA testing by serologic, molecular, or flow cytometry methods. Laboratories performing HLA testing (other than single antigen typing for disease association studies) by flow cytometry will be inspected with both the Flow Cytometry and Histocompatibility Checklists. Checklist items addressing instrument maintenance and quality control for flow cytometry methods are included in the Flow Cytometry Checklist.

Inspector Qualifications: Inspectors of a histocompatibility laboratory must be pathologists, clinical scientists, or medical technologists who are actively involved with or have extensive experience in the practice of histocompatibility testing and are knowledgeable about current CAP checklist and corresponding CLIA '88 requirements. CAP histocompatibility inspectors should have the qualifications for technical supervisors of a CAP-accredited histocompatibility laboratory or have experience in a supervisory position and at least five years experience in clinical histocompatibility. The inspector should have experience in a laboratory similar in size and scope of work to the laboratory being inspected. Major areas that define the scope of work include:

Clinical
- Stem cell (progenitor cell) transplantation using related donors only
- Stem cell (progenitor cell) transplantation using unrelated donors
- Renal transplantation
- Extra-renal transplantation

Technical
- Serologic typing, crossmatching, and antibody identification
- Flow cytometry, crossmatching, and antibody determination
- DNA analysis (e.g., SSP, SSOP)
- DNA sequence-based typing

A list of histocompatibility specialty inspectors is provided to the inspection team leader in the Inspector's Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP Inspector Database Specialist at 800-323-4040, extension 7380, for the names of additional qualified inspectors.

Before the Inspection: The Inspector's Inspection Packet contains information about the laboratory's scope of histocompatibility activities and personnel qualifications. Thoroughly review these materials, along with the Histocompatibility Checklist. If an inspector determines that the scope of the laboratory is such that he or she does not feel qualified to inspect it, the team leader should be contacted immediately. LAP staff can assist the team leader in locating additional histocompatibility inspectors if needed.

Allow sufficient time for the inspection. Laboratories performing stem cell and multiple organ transplants usually require one full day for an inspection.

The types of tests the laboratory performs and the clinical programs it supports will guide the evaluation of personnel qualifications and continuing education activities.

Some of the Histocompatibility Checklist items have NOTES following the questions. These NOTES

contain additional information to enhance the understanding of the intent of the checklist item within the context of the laboratory being inspected.

During the Inspection: The inspector must address all checklist questions. Be thorough but efficient, completing the inspection in a reasonable period of time.

Quality Control and Proficiency Testing: Proficiency testing results and QC for all tests performed should be reviewed in detail with emphasis on documentation of corrective action. It is important that the inspector verify that the laboratory participates in proficiency testing programs accepted by the College's Commission on Laboratory Accreditation.

Leadership: Policies and procedures should clearly explain how the laboratory leadership addresses the following issues: Testing quality; level of testing according to clinical need; repeat testing; and which technique to use in specific cases when more than one technique is available. The degree of involvement of the supervisor and director should be evaluated.

Reports: Reports vary considerably among histocompatibility labs and should be reviewed for correct use of nomenclature, accurate description of the tests performed, and meaningful final interpretation of the results.

Personnel: Evaluation of the expertise and training of personnel must take into account the tests performed and the transplant programs the laboratory supports. The inspector must determine if the policies to assess personnel competency are appropriate. There must be documented evidence of sufficient continuing education credits for directors, supervisors, and other technical personnel.

Inspection Resources*:* Technical specialists in the CAP office are available to assist with questions concerning checklist interpretation before or during the course of the inspection. Call 800-323-4040, option 2, option 2, between 8 AM-5 PM Central Time.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Inspecting the Histocompatibility Laboratory" audioconference.

Immunology (IMM)

Inspection of Immunology is not limited to the contents of the Immunology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

New kits and reagents must be checked against old lots to ensure comparable reactivity before or concurrently with being placed in service. For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative patient sample from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot. Good clinical laboratory science includes patient-based comparisons in many situations, since it is patient results that are "controlled."

For qualitative tests, positive and negative controls must be run and documented at least once each day of analysis, based on the manufacturer's recommendations. For quantitative tests, control samples at more

than one level must be run at least once each day of analysis. When results are reported as “weakly” positive, a weakly positive control should be used.

Certain immunologic reagent/kit systems include internal positive and negative controls. If so, external matrix-appropriate controls are required with each new lot number or new shipment of a lot number. At a minimum, manufacturers' recommendations must be followed. For panels or batteries, controls must be employed for each analyte sought in patient specimens. If internal positive and negative controls are NOT present, a **positive and negative control must be tested each day of analysis for all qualitative or semi-quantitative antigen/antibody tests.** The checklist provides clarification of when controls must be evaluated.

Waived Test Requirements*:* Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 35).

Microbiology (MIC)

Inspection of Microbiology is not limited to the contents of the Microbiology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Microbiology Checklist is divided into six subsections: Bacteriology, mycobacteriology, mycology, parasitology, virology, and molecular microbiology, as well as an initial general section applicable to all subspecialties. Judgment is required on the part of the inspector to determine whether the level of service is appropriate to the institution’s needs. Laboratories serving larger institutions will likely provide all services for the subsections listed above. Smaller laboratories may still meet the *Standards of Laboratory Accreditation* by providing reliable preliminary screening and/or identification and then referring specimens or cultures for more definitive analysis to a reference laboratory when necessary for patient management.

Proficiency Testing: The microbiology laboratory must match its proficiency testing organism reporting level to the same degree used in patient reports. If the laboratory's proficiency testing reports include incomplete identifications (e.g., "Gram positive cocci" or "Mycobacterium species, not tuberculosis"), it must document that this matches the information produced by the laboratory's internal capabilities in patient reports. In other words, patient reports cannot be more specific than the identification level reporting in proficiency testing, unless the more specific information is provided by reference laboratories.

Quality Control: This section includes QC requirements for prepared and purchased culture media, staining procedures, reagents, antimicrobial susceptibility tests, instruments, and equipment. For each procedure, medium, reagent, and item of equipment to be monitored, the control methods should be defined, as well as the frequency of testing, limits for acceptability, and action to be taken when not acceptable.

In October 2003, the CAP microbiology QC requirements were modified to match those of the CLIA ’88 final quality control rule. In some cases, CAP requirements became more stringent, in some cases less

stringent, and in others the CAP QC requirements stayed the same. Details of the QC changes are summarized in table format in the microbiology subdisciplines that follow.

Media: The inspector should review the following in regards to commercially prepared culture media:

- The laboratory must ensure that all media used, whether purchased or prepared in-house by the laboratory, are sterile, able to support growth appropriately, and are appropriately reactive biochemically.
- For laboratories preparing their own media, it will be necessary to maintain stock or reference organisms and to test the media before, or concurrently, with use. Explicit documentation of such testing is essential and must be retained for at least two years.
- For prepared, purchased media the laboratory must have explicit documentation that each lot is tested for ability to support growth of appropriate organisms and biochemical reactivity at the time of receipt or concurrent with use in the laboratory. The user must control the media for reactions that are not tested by the preparer (e.g., proper function of sheep blood agar for the CAMP test).
- Laboratories that rely on manufacturers' QC of media should have a copy of the CLSI document M-22-A3, *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The manufacturer or preparer must supply documentation to the user that its QC activities meet the CLSI guidelines. For each lot, the preparer should certify that QC performance was acceptable and a record of the lot numbers for all media is retained for at least two years. The user laboratory may record that fact in place of the more detailed documentation of media performance.
- The user must visually examine each shipment for breakage, contamination, appearance, or evidence of freezing or overheating.
- The user must continue to test each lot of media not listed specifically in M-22-A3 as being exempt from such testing, for ability to support growth, and appropriate biochemical reaction using QC methods used for media manufactured in-house.
- In addition, each shipment or lot of a commercial identification system must be tested for appropriate performance.
- The director is responsible for the quality and performance of media and all media failures and the resultant corrective action taken must be documented.
- QC of antimicrobial susceptibility tests is accomplished by monitoring the performance of the test system with appropriate reference control organisms. Control organisms must be run with each new lot or batch of antimicrobials or media, and daily thereafter. The QC frequency may be reduced from daily to weekly once satisfactory daily performance for 20 or 30 consecutive days is documented. Whenever weekly tests yield unacceptable results, daily QC testing must be performed until the cause of the unacceptable results is determined and resolution of the problem is documented. Before returning to a weekly QC frequency, the laboratory must document five consecutive days of satisfactory quality control results.
- The director is responsible for developing and implementing a system to ensure consistency among all personnel that perform Gram and other organism stains.

Bacteriology: The inspectors' discretion is necessary to evaluate a laboratory's protocols for specimen work-up and identification of organisms and test systems. For example, no specific requirements are listed for the extent of work-up of specimens such as sputum, urine, stools, and wounds. Policies should be mutually acceptable to the medical staff and the laboratory. Selection of antibiotics to be tested and reported with each antimicrobial susceptibility test requires input from the pharmacy department and the medical staff. For hospital-based microbiology laboratories, cumulative antimicrobial susceptibility test data should be maintained and reported to the medical staff at least yearly.

The inspector should assess the adequacy of the blood culture system for detection of microorganisms for the patient population. It is recommended that the laboratory keep blood culture statistics as a monitor of collection techniques, including the number of true positive cultures and the number of contaminated cultures.

Stain Type	Previous Checklist QC Requirement	New Checklist QC Requirement (Minimum)	Frequency Change
Gram Stain	Each batch and at least weekly (using + & - control)		No change
Bacteriology stains (excluding Gram stain) Non-immunologic, non-immunofluorescent	Each day or weekly (whichever is less frequent), for intended reactivity	Each day of use and new batch/lot/shipment (using + & - control)	Increased
Fluorescent	Each time of use (using + & - control)		No change

Reagent Type	Previous Checklist QC Requirement	New Checklist QC Requirement (Minimum)	Frequency Change
Catalase, Coagulase, and Oxidase	Each day of use	Each batch/lot/shipment (using + & - control)	Decreased
Beta lactamase (other than cefinase)	Each day of use		No change
Cefinase beta lactamase		Each batch/lot/shipment (using + & - control)	
Disks or strips*:* Bacitracin, Optochin, X & V	Each week or day of use (whichever is less frequent)	Each batch/lot/shipment (using + & - control)	Decreased
ONPG broth	Each batch or shipment (using + & - control)	Each batch/lot/shipment (using + & - control)	No change
ONPG disks or strips	Weekly (using + & - control)	Each batch/lot/shipment (using + & - control)	Decreased
Antisera	Each month and initially	Each batch/lot/shipment when prepared or opened, and once each six months thereafter	Decreased
Nucleic acid probes	Each day of use		No change
Identification systems for + and - reactivity	No specific item, but addressed in general reagent section comments	Each batch/lot/shipment (using + & - control	No change

***Waived Test Requirements**:* Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 35).

Mycobacteriology: The CAP supports a policy that encourages laboratories to use the most rapid and reliable methods available for detection and identification of mycobacteria, especially *M. tuberculosis.* This is of particular importance in areas where the incidence of tuberculosis is increasing. Questions relating to smears, processing, culture media, identification, and susceptibility testing of mycobacteria are recent additions to the checklist. For microscopic examination of slides prepared from primary patient specimens, fluorochrome stains must be used. The inspector must assess the relevancy of these questions in view of the incidence of tuberculosis in the geographic area or patient population served.

Type of Stain or Reagent	Previous Checklist QC Requirement	New Checklist QC Requirement (Minimum)	Frequency Change
AFB Stains	Each week of use (using + control)	Day of use (using + & - control)	Increased
Fluorescent stain	Each week or day of use; whichever is less frequent, (using + & - control)	Each time of use (using + & - control)	Increased
Iron uptake reagents	Day of use	Day of use (using + & - control)	No change

Mycology: All staining procedures should be checked and results recorded for each new batch of preparations, and at least daily against known positive and negative control organisms. For stains such as Gomori methenamine silver and Giemsa, the slide itself serves as the negative control. Controls for KOH preparations are not required.

Type of Stain or Reagent	Previous Checklist QC Requirement	New Checklist QC Requirement (Minimum)	Frequency Change
All stains*:* Acid fast, PAS, Giemsa, Gomori methenamine silver, India ink	Each day of use (using + & - control)	Each day of use (using + & - control)	No change
KOH preps	No QC required		No change

Virology: The laboratory must have the appropriate minimal cell lines available for all of the virology testing performed in the laboratory; a listing appears in the checklist. Continuous cell lines must be periodically checked for *Mycoplasma* contamination. Media must be checked for sterility if additives are added after initial sterilization. Removal of aliquots for refeeding does not require additional testing for sterility.

Parasitology: Concentration procedures and permanent stained preparations must be performed on all stools submitted for parasitological microscopic examination. A microscopic examination of liquid stools should include a direct wet mount if submitted fresh. Laboratories must have an ocular micrometer available for determining the size of eggs and larvae, and the micrometer should be calibrated for the

microscope in which it is used. The micrometer does **not** require periodic checking if the optical path is unaltered.

Type of Stain or Reagent	Previous Checklist QC Requirement	New Checklist QC Requirement (Minimum)	Frequency Change
Permanent parasitology	At least monthly, or with each test performed		No change
Specific parasitology (acid-fast, fluorescent)	Each time of use		No change

Visit the CAP Web site to hear the "Inspecting the Microbiology Laboratory" audioconference.

Molecular Microbiology: 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.

Laboratories should consult the list of currently FDA-approved tests published online by the Association for Molecular Pathology (AMP) at www.ampweb.org

Molecular Pathology (MOL)

Inspection of Molecular Pathology is not limited to the contents of the Molecular Pathology Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

Checklist Usage: The Molecular Pathology Checklist covers most aspects of clinical molecular testing, including oncology, hematology, infectious disease, inherited disease, HLA typing, forensics, and parentage applications. Testing that involves DNA/RNA probe hybridization or amplification constitutes molecular testing. The inspection of laboratories performing molecular testing requires the Molecular Pathology Checklist, except for the following:

1. The Cytogenetics or Anatomic Pathology Checklist (as appropriate) is used to inspect laboratories that perform fluorescence in situ hybridization (FISH) testing; also, the Anatomic Pathology Checklist may be used to inspect in situ hybridization (ISH).

2. The Microbiology Checklist may be used to inspect laboratories that limit molecular testing to infectious disease testing using unmodified, FDA-approved methods. Microbiology laboratories that use molecular methods that are not FDA-approved, or that modify an FDA-approved method, must be inspected with the Molecular Pathology Checklist. Laboratories should consult the list of currently FDA-approved tests published online by the Association for Molecular Pathology (AMP) at www.ampweb.org.

Inspector Requirements*:* Inspection of a molecular pathology laboratory requires special knowledge of the science. The inspector should be an actively practicing molecular scientist familiar with the checklist

and possessing the technical and interpretive skills necessary to evaluate the quality of the laboratory's performance. A list of molecular specialty inspectors is provided to the inspection team leader in the Inspector's Inspection Packet. The team leader must recruit potential inspectors from this list. If an inspector cannot be identified, contact the LAP Inspector Database Specialist at 800-323-4040, extension 7380, for the names of additional qualified inspectors.

Preparing to Inspect: The inspector must be familiar with the Molecular Pathology Checklist, and should review the checklist prior to the inspection along with the Laboratory General Checklist and any other applicable checklists. If the intent of any checklist question is not clear, the CAP technical staff can offer further explanation or interpretation at 800-323-4040 option 2, option 2, or extension 6065.

Review the Activity Menu: The laboratory's activity menu and instrumentation lists help the inspector understand the type and scope of testing the laboratory is performing.

Quality Control: For **amplification** assays, the inspector will look for negative controls that help detect contamination and cross-hybridization and positive controls that ensure the assay performs acceptably. Internal probes must be used to verify the specificity of the product when appropriate, and tests for amplifiable nucleic acid must be performed as appropriate and feasible. The inspector will check for precautions against contamination, such as physical separation of the patient specimen PCR set-up area from the post-amplification area.

For **Southern blot** analysis, the inspector will check that DNA quantitation and purity are often monitored, as well as the completeness of restriction endonuclease digestion. There should be evidence that fragment size is evaluated by comparison with molecular weight standards, electrophoresis is carried out at standard voltages and times to promote reproducibility, and probes are adequately labeled. Positive, negative, and sensitivity controls must be assayed in each run as appropriate, and interpretive guidelines used to render interpretations.

In situ hybridization (ISH) results are interpreted in the context of tissue morphology. ISH results are usually interpreted in the context of karyotype. There should be documentation that tissue and positive and negative probe controls verify assay sensitivity and specificity. The inspector should check microscope quality to ensure that resolution is sufficient, and that stain results are interpretable. A sampling of cases and controls will be reviewed to evaluate signal, background, and morphology.

The inspector will look to see that **probes and primers** are described in terms of expected fragment sizes, cross-hybridization, relevant restriction enzyme digestion sites, associated positive and negative control cell lines or tissues, and for pertinent literature references. If radiolabels are used, a radiation safety manual must be available and appropriate for the isotopes in use. For linkage analysis, recombination frequencies should be documented.

The inspector will ensure that prior to clinical implementation of a new assay the laboratory has demonstrated analytic validity. This includes requirements to verify or establish accuracy, precision, analytic sensitivity and specificity, reportable range, reference range, and any other required performance characteristics.

Result Reporting: Reports will be examined to verify that results requiring interpretation are signed out by a physician in the context of other available clinical information, such as clinical history, morphologic features, special stains, molecular pathology, and immunophenotype. Interpretation must be done in comparison with controls in each analysis using written guidelines. Reports must contain necessary and

sufficient information for proper clinical decision-making. A narrative interpretation for tests that complement other clinicopathologic data must be included on the report.

As part of **quality management**, the laboratory must study its failed reactions and suboptimal analyses for improvement opportunities. The inspector should ask for the record of such events. There must be documentation that each failure is investigated for cause. Problems such as failed extractions that affect patient care should be reported to the ordering physician as soon as possible and documented in the paperwork.

Analyte-Specific Reagents: Rules in effect November 23, 1998, govern sale and use of analyte-specific reagents (ASRs), including molecular probes used as active ingredients in clinical laboratory tests. The rulings focus on Class I ASRs or kits containing ASRs that are purchased commercially, rather than those produced for in-house use. Commercial manufacturers of ASRs must meet requirements for manufacturing and reporting as detailed in the regulations. For tests using Class I ASRs, the following disclaimer must be appended to the test report: "This test was developed and its performance characteristics determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration." Additional language can be appended to clarify that ASR use does not require FDA approval.

HER2: If the laboratory performs HER2 testing, it should have a documented plan to implement the CAP-approved guidelines. The ASCO/CAP Guideline recommendations for HER2 Testing in Breast Cancer may be found at http://www.cap.org/ and may be periodically revised. An acceptable implementation plan consists of appropriate development steps that may include: (1) review of the guideline document, (2) written evaluation of the laboratory's current relevant policies and procedures, (3) gap analysis of existing policies/procedures, (4) written schedule to address identified gaps, and (5) evidence of implementation of changes. Compliance with the guidelines will be required as of December 31, 2007.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Inspecting the Molecular Pathology Laboratory" audioconference.

Point-of-Care (POC)Testing

Inspection of the Point-of-Care Testing areas is not limited to the contents of the Point-of- Care Testing Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

Point-of-Care Testing (POCT) is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Nurses and other personnel who lack backgrounds in formal laboratory science typically perform the testing. Examples include kits and instruments that are hand-carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space; these are covered under the Limited Service Laboratory Checklist.

CLIA ’88 classifies tests according to complexity into waived and non-waived categories. The non-waived category is further subdivided into tests of moderate and high complexity.

This checklist covers only tests that are classified as waived or moderately complex (provider-performed microscopy [PPM] is a subset of moderately complex tests). Beginning with the October 2006 edition of the checklist, requirements for quality control, reagents, and calibration are different for waived tests, as compared to moderately complex tests; please refer to the relevant individual POCT Checklist sections for further details. Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and moderately complex tests.

The current list of tests waived under CLIA ’88 may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Waived Test Requirements*:* Certain checklist requirements are now different for waived tests versus non-waived tests. Checklist requirements for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, instruments and equipment, personnel, and safety are the same for both waived and non-waived tests. Refer to the Requirements Common to All Laboratory Sections section.

Tests/instruments that are NOT covered by the POC checklist include all tests classified under CLIA ’88 as high complexity, as well as legal drug testing, multichannel blood cell counters, bacterial cultures, and tests that use instruments requiring high levels of maintenance or technical skill. The CAP office may be contacted for information about whether a specific test or instrument may be inspected using the POC checklist.

If a POCT site has a scope of service in a particular laboratory discipline that exceeds those addressed in this checklist, then a section-specific checklist (e.g., hematology, microbiology) may be required. Blood gas testing requirements have been added as a new section to the POCT Checklist, to be used to inspect blood gases done at the point of care or near patient testing.

The POC Checklist does not cover patient self-testing. The CAP Laboratory Accreditation Program does not inspect or accredit patient self-testing.

To be accredited, all analytes being measured under the POCT program/site must be included in the on-site inspection. POCT programs may be inspected as sections of the central laboratory if they are registered under the same CLIA ’88 number. In this circumstance, they are included in the Laboratory General and Team Leader checklists used for the central laboratory. If the POCT sites are registered under separate CLIA numbers, separate Laboratory General and Team Leader checklists must be completed for each POCT program. The POCT program may be centrally coordinated, with designated qualified personnel who review testing procedures and quality control, and conduct training of the testing personnel, although this is not a requirement.

When records are maintained centrally by a designated coordinator or POCT director, only one copy of the Point-of-Care Testing Checklist need be completed. The inspector will review all centrally maintained records and visit at least a sampling of the testing sites in order to evaluate compliance with the standards. Therefore, the POC locations must be identified in the application/reapplication process. If records are not maintained centrally, the inspector must visit each POCT site, and a separate checklist must be completed for each location. In the latter case, each POCT site will be inspected as an additional laboratory section.

Each person performing POCT must maintain satisfactory levels of competence. Competency must be reassessed at least annually. During the first year that an individual is performing such patient testing, competency must be assessed every six months. The Personnel section of the POCT Checklist indicates six elements of competence. All the elements that are applicable to an individual's duties must be evaluated for that individual. The competency of physicians who perform POC tests may be established and reassessed through the credentialing process of the institution's medical staff.

Physician-performed testing (PPT) is defined by the College of American Pathologists as testing that is personally performed by a physician in conjunction with the physical examination or treatment of a patient and is limited to the 14 tests mentioned in this section. Patient management is often facilitated by immediate and direct physician performance of certain laboratory tests at the time of a patient encounter. Although these tests may be simple to perform, standards must be maintained to ensure correct results. The other sections of the Point-of-Care Testing checklist do NOT apply to PPT.

The PPT section of the POC Checklist should be completed only if both of the following conditions are true:

1. PPT is performed under the same CLIA number as the laboratory, and
2. The laboratory director is responsible for competency assessment of the physicians.

If the competency of physicians is established and monitored by the credentialing process of the institutional medical staff, then the PPT section may be omitted.

The PPT category is NOT the same as the U.S. CLIA '88 term "provider performed microscopy" (PPM), which allows certain tests to be performed by non-physicians. Rather, it includes (but may not be limited to) both "waived" tests under CLIA '88 and PPM, but only when either is performed by a licensed physician. PPT is currently limited to the following tests:

1. Amniotic fluid pH
2. Vaginal pool fluid smears for ferning
3. Fecal leukocytes
4. Gastric biopsy urease
5. Nasal smears for eosinophils
6. Occult blood, fecal and gastric
7. Pinworm examination
8. Post-coital mucus examination
9. Potassium hydroxide (KOH) preparations
10. Semen analysis, qualitative
11. Synovial fluid for crystals
12. Urine dipstick
13. Urine sediment microscopy
14. Vaginal wet mount microscopy

Visit the CAP Web site Virtual Library of Audioconferences to hear the "POCT and CAP Accreditation" audioconference.

Transfusion Medicine (TRM)

Inspection of Transfusion Medicine is not limited to the contents of the Transfusion Medicine Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

The Transfusion Medicine Checklist emphasizes proper procedure in specimen collection and handling, maintenance of records, monitoring of instruments and equipment, test performance, and verification and documentation of reagent performance.

Component Accession and Disposition Records: Component records must be traceable from inventory to disposition. It must be possible to account for every unit in the records, including quarantine, ultimate disposition, wastage, and incineration. For transfusion services, it must be possible to identify the patient receiving a given unit.

Technical Procedures: Blood typing and compatibility procedures should be directly observed by the inspector to see if actual practice corresponds to the procedure manual. New test systems and reagents must be validated by the laboratory prior to use. Records for such changes should be reviewed during the course of the inspection.

Blood and Blood Components: If blood and blood components are prepared or modified, the processes should be reviewed to ensure proper product labeling to include all FDA-required information, correct assignment of expiration dates, maintenance of the sterility of the components, and appropriate quality control. A physical inspection of refrigerators, freezers, and other equipment used to store blood and blood components must be performed to verify proper storage conditions and appropriate organization within the storage units. Temperature and maintenance records, including alarm checks should be reviewed carefully for deviations and appropriate corrective actions. The checklist requirements apply to storage units within the transfusion service, as well as blood storage areas located within the facility (e.g., surgery, nursing, dialysis units, etc.).

Store and Issue of Tissues: If the transfusion service is involved in the procurement and processing of tissue, other than blood, the laboratory's authority and responsibilities in the program must be defined. Records must be maintained to document appropriate storage conditions, as well as disposition.

Transfusion: Patient care activities should be observed, with particular emphasis on patient identification and blood component administration procedures. The transfusion service must actively monitor key elements of the transfusion process and have a system to reduce the risk of mistransfusion. Those off-site activities that interface directly with the laboratory, such as blood transfusion and maintenance of remote refrigerators, should be observed as a measure of the effectiveness of laboratory communication. Transfusion reaction records and similar clinical pathology consultation should be reviewed carefully.

Donor Procedures and Apheresis: If donors are drawn and/or units are processed at the facility, each step should be evaluated, including the details of the donor interview, phlebotomy, and storage/release/quarantine procedures. If infectious disease testing is done, the adequacy and appropriateness of procedures should be reviewed, regardless of where in the facility this is performed.

Bone Marrow and/or Progenitor Cells: This section is intended for laboratories involved in the collection, processing, storage, and reinfusion of bone marrow and/or progenitor cells.

AABB Coordinated Inspections: In some cases, a hospital transfusion service or blood bank may apply for dual accreditation by the CAP and the AABB. While compliance with the current edition of the Standards for Blood Banks and Transfusion Services of the AABB also represents good laboratory practice, accreditation by the AABB and the CAP are separate events. Therefore, if an AABB inspection is performed simultaneously with a CAP inspection, all questions in the Transfusion Medicine, Laboratory General, and other CAP checklists (as applicable) must be addressed to qualify for accreditation by the CAP.

Visit the CAP Web site Virtual Library of Audioconferences to hear the "Inspecting the Transfusion Medicine Laboratory" audioconference.

Urinalysis (URN)

Inspection of Urinalysis is not limited to the contents of the Urinalysis Checklist, but includes all applicable portions of the Laboratory General Checklist (GEN). All sections of the laboratory must be familiar with and in compliance with the requirements of the GEN Checklist. See the Laboratory General and Safety sections of this accreditation manual, as well as the areas Conducting the Inspection and Requirements Common to all Laboratory Sections.

Specimens: Instructions must be provided for proper collection of clean voided urine specimens that avoids deterioration of constituents. Specimens must be examined within one-two hours of collection unless properly preserved. Simple refrigeration may not be adequate, as it will not prevent the lytic effects of low specific gravity on sediment elements and may induce crystal formation.

Manual Tests: Refractometer calibration must be periodically verified with at least two solutions of known specific gravity. While the definition of a "complete" urinalysis is at the discretion of the laboratory, and dependent upon the population tested, the following chemical constituents are considered important: Glucose, protein, blood or hemoglobin, nitrite, and leukocyte esterase. There should be documented criteria for when a routine urinalysis does not require sediment microscopy. As sediment is commonly viewed without stains, microscopes must be in excellent condition, and with Köhler illumination maintained for bright-field microscopy. Dipstick findings should be correlated with microscopy. The laboratory should have a system that ensures that all personnel report microscopy morphology in a similar fashion. Suggested methods to accomplish this include:

- Circulation of preserved urine sediments with defined abnormalities involving leukocytes, erythrocytes, bacteria, yeast, and/or
- Multi-headed microscopy, and/or
- Use of urine sediment photomicrographs with referee and consensus identifications, such as those from former CAP Surveys.

Automated/Semi-automated Tests: There should be documented criteria for identifying urine samples that may give erroneous results with a dipstick reader. Automated imaging systems must be carefully compared with manual microscopy before used for patient reporting, and cell count controls must be processed on each shift of patient testing.

Waived Test Requirements: Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 35).

INSPECTING OTHER TYPES OF LABORATORIES

Special Function Laboratories

- Special function laboratories are administered independently of and have different CLIA numbers than the main clinical laboratory, generally employ fewer personnel, and are dedicated to the performance of a highly select group of clinical procedures. If within 15 miles or 30 minutes driving distance from the main clinical laboratory, special function laboratories are assigned to the same inspection team. Examples of special function laboratories include, but are not limited to, blood gases performed by respiratory therapy, and special hematology analyses in pediatrics or oncology clinics.
- **At least three checklists are required—the Laboratory General Checklist, the Team Leader Assessment of Director & Quality Checklist used by the team leader inspecting the main laboratory, and the checklist(s) appropriate to the specific function(s).** The inspection is scheduled concurrently with the main laboratory inspection**.**
- Special function laboratories may request their own Summation Conference.
- The special function laboratory and main laboratory accreditation process and decision are made independently.
- The hospital administrator and a representative member of the medical staff will be interviewed for every special function laboratory within a hospital.

Affiliated Laboratories

- Affiliated laboratories are located at physically separate sites but are affiliated by management and/or ownership.
- Each site is considered a separate laboratory and has an individual CLIA number. Each site will receive separate inspection fees, materials, checklists, and a separate certificate of accreditation.
- Examples of affiliated laboratories are: (a) two or more merged hospitals that provide some services at each site (one often designated as full service and the other as rapid turn); (b) a large commercial laboratory that has branches in different geographic locations; or (c) remote limited service or special function laboratories.
- **Affiliated laboratories that are within 15 miles or 30 minutes driving distance may be assigned to the same inspection team.** The inspection team leader needs to take into consideration the location of these laboratories when they are inspected at the same time as a laboratory with which they are associated, in order to allow time for the inspection and arrange for transportation if necessary.

Satellite Laboratories

- Satellite laboratories are usually small branch laboratories that are affiliated with, but not physically located at the same address as, the central laboratory. They also have their own CLIA number.
- In most cases, the services that are provided correspond with the Limited Service Laboratory Checklist.
- Separate fees, inspection materials, and checklists are required.
- This inspection can occur concurrently with the main laboratory inspection if the satellite laboratory is within 15 miles or 30 minutes driving distance from the main laboratory. The inspection team leader needs to take into consideration the location of the satellite laboratories when they are inspected at the same time as a laboratory with which they are associated, in order to allow time for the inspection and arrange for transportation if necessary.

Staff-inspected Laboratories

- This program is in keeping with the College's philosophy of peer review by using CAP-employed medical technologists to review laboratories that are often performing limited testing. Affiliated and/or satellite laboratories located more than 15 miles or 30 minutes from the main laboratory are typically inspected by CAP-employed medical technologists.
- Hospitals with 100 beds or less that perform basic testing (such as that seen in a core laboratory) may also be inspected by the CAP-employed medical technologists. If there is any on-site anatomic pathology, it must be limited to frozen sections and/or accessioning.

Limited Service Laboratories

- The Limited Service Checklist is provided as a convenience when inspecting a laboratory or a laboratory section whose scope of services is confined to a small number of commonly performed tests covering multiple disciplines. It relieves the inspector and the laboratory of the burden of completing multiple checklists during on-site visits to such laboratories.
- If a site qualifies as a "limited service laboratory" and is a free-standing entity with its own director and CLIA number, the Laboratory General and Team Leader Assessment of Director & Quality Checklists must be used with the Limited Service Laboratory Checklist. In other words, the Limited Service Laboratory Checklist cannot be used alone in that setting.
- On the other hand, if the limited service laboratory is administratively and medically part of a central laboratory at the same site and shares the same federal CLIA number, then one copy of the Laboratory General and Team Leader Assessment of Director & Quality Checklists should suffice for both the central laboratory sections and the limited service laboratory. In such cases, the limited service laboratory is viewed as a multifunctional section of the central laboratory.
- The Master Activity Menu is divided into a basic list and an extended list of reportable assays. Limited Service Checklist usage is determined by the selection of Reportable Assays-Basic List (only) within a subdiscipline. If assays are selected from the basic list and the extended list of reportable assays, the discipline-specific checklist will most often be used.
- The Limited Service Checklist CANNOT be used alone if anatomic pathology, cytopathology, flow cytometry, molecular pathology, histocompatibility, cytogenetics, or point-of-care testing are performed. The inspector must also use the appropriate discipline-specific checklist(s) for these areas.
- LAP staff makes the final determination regarding use of this checklist.

***Waived Test Requirements**:* Certain checklist requirements are now different for waived tests versus non-waived tests. See the Requirements Common to All Laboratory Sections, Waived Test Requirements area of this accreditation manual for specific detail (see page 35).

System Inspection Option

The system option for laboratory accreditation provides laboratory directors the choice to have *multiple* laboratories under the same ownership and administration inspected by *one* team of inspectors using the same checklist versions within a few days of each other. A system is composed of laboratories with highly integrated services meeting specific eligibility requirements. This provides the opportunity for coordinated laboratory preparation and development of common strategies to comply with the CAP requirements and allows key personnel with responsibilities at multiple sites to participate in the on-site inspections.

Definition of a System

A system is defined as two or more full-service laboratories that identify themselves as a system and have common administration and ownership with all laboratories within three (3) hours travel time (ground transportation) of a system-defined central location.

System Option Eligibility Criteria

Each individual laboratory within the system must meet the following criteria:

1. Use the same administrative policies.
2. Report directly to a central management team.
3. Have a common competency policy for common instruments and procedures.
4. Participate in a system-wide continuous improvement plan.
5. Use the same QC interpretive standards and guidelines for common instruments and procedures.
6. Have an integrated information/central data repository or common laboratory information system (LIS).
7. Participate in a common safety program with a common safety manual.
8. Use a common specimen collection manual.

The degree of integration within the system is a major determinant in a system meeting eligibility requirements and thereby remaining in the system option.

Pre-inspection Activities

Approximately six to nine months prior to the laboratory's anniversary date, an LAP Inspection Specialist will conduct a pre-inspection visit or a conference call to determine the System's level of integration of services. The LAP Inspection Specialist will dialogue with members of the System Administration and Management team to gather information and to better understand the logistical requirements for the upcoming inspection. The information obtained by the Inspection Specialist will be forwarded to the team leader to assist with inspection planning and the team building process. Examples of the tools that will be used during this visit are available at the CAP Web site at www.cap.org.

Preparing to Perform a System Inspection

In general, the inspection process is similar to that required to inspect a single laboratory/facility. However, team size and composition require particular attention and planning. Travel and lodging can be complex; therefore **use of the CAP Travel Desk agents at 800-323-4040, extension 7800, is required for all air travel and hotel accommodations.** The CAP Travel Desk agents will arrange for direct billing of airfare and lodging, and will negotiate the best rates for both.

Upon receipt of the inspector's packet and the pre-inspection report, the team leader will determine how many inspectors and how many days will be needed to complete the inspection. The CAP recommends that inspection teams use inspectors who can inspect multiple areas; this will decrease disruption of services at the laboratory and will decrease on-site inspection costs. To assemble your team, please use the information sent to you by the inspection specialist who performed the pre-inspection visit, and the team building spreadsheet tool that is included in the packet. (An electronic template can be found on the System CD.) Share your plans with the Inspection Specialist and the LAP Inspection Assignment Specialist to determine if there is agreement on team size, composition, time allocation, and the preferred

week the inspection will occur in accordance with the Inspection Specialist's schedule.

Prepare for the inspection well before the inspection dates. Be clear on what is and is not to be inspected. For instance, a system with a central histology/cytology processing location but with frozen section and/or interpretive services provided at multiple locations requires on-site inspection of each laboratory using the appropriate portions of the Anatomic Pathology and/or Cytopathology Checklists. All Inspector's Summation Report pages are to be addressed during the inspection. If you believe a page is not needed, contact the Inspection Specialist assigned to your team to explain your rationale and thereby reduce the need to perform reinspection(s).

A coordinated inspection with the American Association of Blood Banks inspector is pertinent only to the laboratory that has dual CAP/AABB accreditation. There may be other laboratories in the system providing transfusion services that are CAP-accredited but not AABB-accredited. These must be inspected by member(s) of the CAP system inspection team. If you have any questions either as you prepare for the inspection or at the time of the on-site inspection, call 800-323-4040, extension 6065, to consult with a technical specialist in the Laboratory Accreditation Program.

Review the remainder of this manual for additional information on preparing for and performing a CAP inspection.

Inspection Tools Specific to Systems

One of the goals of a system inspection is to provide continuity in the inspection process. Therefore, the inspector who inspects a given discipline should be the one inspecting this discipline in all labs. However, there are times when this is not possible; in these settings, all inspectors inspecting the same discipline must discuss the findings between laboratories to ensure a consistent approach and interpretation of compliance.

Supplements to the Systems Inspector's Inspection Packet

1. The **Assessment of System Integration Form** is completed by the Inspection Specialist during the pre-inspection visit, and the completed form will be forwarded to the team leader to assist in team building. The criteria can be used during the global summation conference to discuss the degree of system integration.

2. **Planning Guide for Inspector Areas of Responsibility** is available as an Excel spreadsheet and can by found on the System CD-ROM in your packet. The team leader uses this form to build the team and ensure adequate inspectors are used, as well as ensuring any specialty inspector needs are met. A paper copy of this document is also included in your packet. The paper copy is customized for the system you are inspecting. The electronic form on the CD-ROM is a generic template.

3. **System Integrated Inspector's Summation Report** is an Excel spreadsheet that will summarize deficiencies and recommendations to facilitate the global summation conference. An example of this document can be found on the System CD. The Inspection Specialist accompanying the inspection team will maintain this document and provide a completed copy to the team leader prior to the global summation conference.

Visit the CAP Web site to hear the "Systems Inspection Update" audioconference.

THE SUMMATION CONFERENCE

The Summation Conference may be the most important part of the on-site inspection. It is the final opportunity for interaction between the inspection team, the laboratory staff, and administration.

Pre-summation Team Meeting

An effective Summation Conference begins with the pre-summation preparation, a 30-60 minute private meeting of the team leader and the inspection team members. The goal of this meeting is to ensure that both the verbal and written inspection reports are complete and consistent. This meeting provides an opportunity for all the team members to share their overall impressions of the laboratory. This will assist the team leader to complete Part A of the ISR and provide a brief review of the cited deficiencies.

- The team leader should remind team members to record the deficiencies in a clear, concise, straightforward manner, relating each to concrete information gathered during the inspection process.
- **The *pink* pages of Part B of the Inspector's Summation Report (ISR) are used to list deficiencies. For each page, the inspector should record the individual checklist item number and a brief description of the reason for the deficiency, providing details about the nature of the non-compliance. State the finding, *not* the checklist question! Reference to a specific policy, analyte, or laboratory record allows the laboratory to more specifically address the cited deficiency. This is the official record of the inspection and must be readable for accurate documentation and appropriate follow-up.**
- **Recommendations should be listed on the appropriate yellow pages of the ISR.**
- All deficiencies should have been discussed with appropriate supervisors. If, because of this discussion with the supervisor, appropriate documentation is provided to show the laboratory is actually in compliance, the deficiency will not be cited.
- On the other hand, if the deficiency is corrected on-site, the deficiency remains on the ISR with the inspector adding the written notation "corrected on-site, substantiated by _____(the inspector must fill in the detail regarding how the lab corrected the deficiency); no laboratory response required." The CAP reserves the right to request documentation from the laboratory concerning how the deficiency was corrected on-site.
- The team leader should provide help in resolving any remaining questions the inspection team members might have. For assistance, contact a technical specialist at the CAP at 800-323-4040, extension 6065.

Before concluding the pre-summation meeting, the team leader should check that:

1. All areas of the laboratory have been inspected.
2. Every inspection team member has completed a deficiency report (pink sheet) that corresponds to the laboratory section(s) for which he/she is responsible.
3. Appropriate checklist items have been cited and the correct deficiency numbers listed on the pink deficiency sheets.
4. The "No Deficiencies" box has been checked when applicable.
5. No deficiency forms (pink sheets) or recommendations forms (yellow sheets) have been left blank or unsigned. If there are no recommendations for a particular section, write "none" on the recommendations form.

Summation Conference

Process and Format of the Conference

- The Summation Conference should be scheduled for a time when personnel involved in the inspection can attend, such as the end of the workday.
- Invitations to attend the Summation Conference should be extended to the laboratory director and laboratory personnel, as well as the administration and the chief of the medical staff, if applicable.
- The team leader should introduce the inspection team members, noting their inspection assignments.
- The team leader should state that the objectives of the Laboratory Accreditation Program are to improve the laboratory for the benefit of the patient through a voluntary, educational peer-review process.
- Regulatory requirements must be met, but these are not the only goals of the program, which is recognized as the gold standard in laboratory medicine. The primary objective is not to find deficiencies, but to validate the on-going laboratory processes and assess their compliance with CLIA '88 and CAP checklist requirements. The inspection team will identify areas for improvement by citing deficiencies, share information regarding how other laboratories accomplish compliance, and make recommendations for possible changes to the laboratory patient care services.

Presentation of Deficiencies

- The laboratory should encounter no surprises when the ISR is discussed. Findings should have been discussed with the laboratory supervisors during the inspection.
- Each team member should begin with a brief self-introduction and a word of thanks for the staff that assisted them in the inspection process. Then each member should briefly present, in a professional manner, the findings of their inspection, including the deficiencies they identified and areas where they felt that the laboratory did particularly well. There should be adequate time allowed to present findings and answer questions.
- The Summation Conference is also an appropriate time to discuss recommendations for improvement, as time permits.
- Any unresolved differences concerning interpretation of the *Standards* or checklists items should be addressed at this time. Unresolved differences should be documented in the ISR and left for the Regional Commissioner to review.
- Unresolved differences and challenges to any deficiency should be pursued by the laboratory director in the laboratory's deficiency response. This should include supporting documentation that will demonstrate full laboratory compliance prior to inspection. Challenged deficiencies are referred to the Regional Commissioner for possible removal from the record.
- The differences between Phase I and Phase II deficiencies should be reviewed. Phase I require a written response, whereas Phase II deficiencies require both a written plan of corrective action and supporting documentation that demonstrates that the plan was implemented. Examples of documentation should be given: Policies or procedures edited appropriately and signed and dated by the laboratory director or documented designee; QC or maintenance records; log sheets with data; instrument printouts; purchase orders; photographs; memos signed by recipients; meeting minutes

with attendance noted; and e-mail memos with distribution list and a list of those who have read them.
- No response or corrective action is required for recommendations, but a recommendation should be reviewed as a suggestion for improvement.
- The post-inspection process is reviewed. Remind the laboratory that **deficiency responses**, including documentation of corrective action, and documentation of the laboratory director's approval of the responses, **must be submitted within 30 calendar days of the inspection date. There will NOT be a formal list of deficiencies sent from the College to initiate the laboratory's corrective action and response to the CAP.**
- The laboratory should submit their deficiency response and retain a copy in the laboratory.
- Remind the laboratory that response forms and instructions were sent to the laboratory director and can be printed from www.cap.org if needed. Explain that 75 days after inspection is the timeframe for receiving an accreditation decision.
- **Both the laboratory director and the inspection team leader must sign the ISR.**
- The team leader should express the team's gratitude and extend congratulations to the laboratory and its staff for participation in the program and their work in preparing for and participating in the inspection. Acknowledge the hospitality and cooperation of the staff during the process.

Visit the CAP Web site Virtual Library of Audioconferences to hear "The Summation Conference" audioconference.

Concluding the Inspection

The team leader should:
- Give an approximation of the total number of checklist questions that were used (each checklist consisting of 300 questions or more) to inspect the laboratory so those in attendance can put the number of identified deficiencies into perspective.
- Thank the director for supporting the LAP process.
- **Photocopy each page of the ISR Part B and leave the copy with the laboratory director.**
- **Place the pink and yellow ISR pages in the pre-paid mailing envelope and return to the CAP within two days of the inspection. This mailer can be used in the 48 contiguous states.** Materials from inspections outside the 48 states (e.g., overseas countries, Alaska, and Hawaii) should be returned to the CAP by the most reliable, traceable service available.
- Remaining forms, including the Inspection Team Member Form (mandatory for CME/CE credit/hour), Claim for Inspection Reimbursement, Team Leader/Member Evaluation Forms, and signed state-specific forms (if applicable) may be returned to the CAP with the ISR or later.
- **Discard at the laboratory the checklists that were used as working documents during the inspection; other inspection materials can be discarded confidentially (i.e., shredded).**
- Send a post-inspection letter thanking the director for the laboratory's hospitality.

The College performs the remaining steps of the accreditation process:

- Using the information provided by the inspector, a technical specialist evaluates the deficiency response for appropriateness and completeness. If additional information is needed to evaluate compliance, an inquiry is faxed to the laboratory director, requesting that documentation be sent to the CAP within 10 days.
- The additional documentation is then forwarded to the Regional Commissioner.
- The Regional Commissioner may request additional information prior to making an accreditation decision. This may include changing a recommendation to a deficiency in cases where the laboratory is clearly non-compliant.

Once an accreditation decision has been made by a CAP Regional Commissioner, an Accreditation Packet will be mailed to the laboratory. The Accreditation Packet includes:

1. Certificate of Accreditation
2. Letter of Accreditation that includes a list of accredited LAP disciplines/subdisciplines and CMS specialties/subspecialties
3. Final List of Deficiencies
4. Press Release

THE INSPECTION REPORT

Inspector's Summation Report (ISR)

Part A of the ISR is used to report any fundamental disparities between the intent of the *Standards* and the activities of the laboratory or the role of the director**. This is confidential information that does not go to the laboratory.** It is reviewed only by the technical specialist, the Regional Commissioner, and the next inspector.

> The inspector's confidential comments, present in Part A, are pivotal in accreditation decisions, particularly those relating to denial of accreditation.

Part B of the ISR includes the deficiencies cited and the recommendations from the team. A copy of Part B of the ISR must be left with the laboratory director. If a deficiency was corrected on-site before the Summation Conference, the inspector should write "corrected on-site" next to that deficiency, and include how the deficiency was corrected. A blank ISR page and a blank recommendation page are provided for contingencies; for instance, reporting the inspection of testing that was not indicated by the laboratory in its reapplication. The inspector must also provide an explanatory comment in the ISR regarding any unexpected testing encountered, as well as if an inappropriate checklist is included in the packet.

> **The inspector is encouraged to contact CAP staff prior to or during the inspection if questions arise regarding the ISR pages, checklist usage, or unexpected items in the laboratory's activity menu.**

If after the on-site inspection the inspector realizes something was left out of the ISR, a letter must be written to the CAP office explaining the addition, and a copy sent to the laboratory director.

Inspection Team Member Form

This form captures the team member demographic information, which is then updated in the CAP Inspector database. Please write legibly and spell correctly. The inspector's institutional address is preferred, rather than a home address.

Inspection Continuing Medical Education (CME) and Continuing Education (CE)

Continuing Medical Education (for pathologists) or Continuing Education (for non-pathologists) is awarded upon request for performing an inspection. A CME/CE Certificate Request Form is provided and must be completed by each inspector desiring credit. Each team member name must be legibly printed with correct spelling, and the appropriate box checked to indicate whether CME or CE credit/hours should be awarded. A certificate is then mailed to the inspector.

Accreditation Statement: The College of American Pathologists (CAP) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

CME Category 1: The College of American Pathologists designates this educational activity for a maximum of seven (7) *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CE (Continuing Education for Non-physicians): The College of American Pathologists designates this educational activity for a maximum of seven (7) credits/hours of continuing education per inspection. Participants should only claim credit commensurate with the extent of their participation in the activity.

This activity is acceptable to meet the continuing education requirements for the ASCP Board of Registry Certification Maintenance Program.

This activity is approved for continuing education credit in the states of California and Florida. California Licensed Medical Technologists may apply the Summation Conference portion, a maximum of two credits/hours, toward the requirements for California State Licensure.

Expense Reimbursement

Reimbursement expense claims for all team members may be returned to the CAP office with the inspection packet or later. **Return of the completed ISR should not be delayed while waiting for the collection of expense information**. This can result in a delay in the accreditation process for the inspected laboratory.

The Claim for Inspection Reimbursement Form includes instructions for expenses that are reimbursed, maximum allowable expenses, and receipt requirements, and should be submitted within 90 days of the inspection.

Team Leader and Team Member Inspection Evaluation Forms

Critique of the inspection process and experience by both team leaders and team members represents essential feedback to the LAP and makes program and process improvement possible.

Return of Inspection Packet

To return the inspection report from anywhere in the U.S. (including Alaska, Hawaii, and Puerto Rico), a DHL pre-paid return label is provided:

- Take the shipment to your institution's mail center for pick-up by DHL, or
- Give the shipment to any DHL driver making a regular pick-up, or
- Take it to any DHL authorized shipping location. Use either the Web site www.dhl-usa.com or call 800-CALL-DHL (800-255-5345) for the nearest location.
- For a special pick-up, use the Web site www.dhl-usa.com or call 800-CALL-DHL at the number above.

<u>After the inspection, discard all other inspection packet materials, including the used checklists</u>. Shred all laboratory-specific information before discarding it in order to maintain confidentiality.

POST-INSPECTION PHASE

Responding to Deficiencies

Before the on-site inspection, the laboratory will receive a Laboratory Inspection Packet that contains a:

- Set of instructions for completing responses to any deficiencies cited during the inspection;
- Blank deficiency response sheet;
- Deficiency response signature page to be signed by the laboratory director and returned with the response;
- Laboratory Specific Activity Menu for the laboratory's review;
- Checklist Selection Report identifying the checklists that will be used at the on-site inspection;
- Set of customized checklists that reflect the activity menu provided by the laboratory during reapplication; the customized checklists are identical to those that will be used by the inspection team.

Additional copies of the signature page and deficiency response sheets are available at the CAP Web site and electronically on the CD-ROM provided with the application and self-evaluation materials.

A copy of the deficiencies and recommendations is provided to the laboratory at the conclusion of the inspection. **This copy serves as the laboratory's sole reference for responding to deficiencies. The CAP will provide no additional printed summary**. **The laboratory must submit appropriate responses to the CAP within 30 calendar days** following the inspection. Failure to respond may result in denial or revocation of accreditation.

Phase I deficiencies require correction and a written response, but supportive documentation of deficiency correction is not required.

Phase II deficiencies require correction, a response, **and supporting documentation of corrective action.** The corrective action must meet with the approval of the Commission on Laboratory Accreditation before accreditation is granted.

Some examples of supporting documentation include but are not limited to: New or revised policies and procedures; log sheets with evidence of use; internal memos, photographs, floor plans, blueprints, purchase orders, and meeting minutes. Respond to each deficiency using a separate response form page. To each response form page, attach appropriate documentation of deficiency correction, labeling each page of the documentation with the deficiency item number (e.g., GEN.10000.) Documentation should be submitted in the order the deficiencies were cited in the ISR. It is recommended that updates and changes to existing documents be highlighted. Patient identifiers should be removed from documentation prior to submitting it to the CAP, whenever possible.

Challenging a Deficiency

Deficiencies cited by the inspection team may be challenged. Dialogue between the laboratory director and the inspection team leader strengthens the program and can provide insight to both the director and the team leader. Such discourse may lead to changes in checklist questions or clarification of requirements.

The response to a disputed citation must note that the citation is disputed and should include a statement outlining the nature of the challenge and documentation that demonstrates that the laboratory was in compliance prior to the inspection. Do not modify current practice if challenging a deficiency. Acceptance of a challenge and subsequent deficiency removal is at the discretion of the Regional Commissioner. If the challenge is not accepted, additional documentation showing correction of the deficiency may be required, and the deficiency will appear in the listing of deficiencies routinely included in the accreditation packet. **Deficiencies that have been approved for removal by the Regional Commissioner will not appear on the final list of deficiencies and are not part of the permanent inspection record.**

Deficiencies Corrected On-site

Some deficiencies may be corrected while the inspectors are still on-site. **Correction on-site is a relatively rare occurrence**, and would include minor corrections such as signing one or two procedures, inserting minimal changes in a procedure, or writing a policy to match existing practice. Other more extensive deficiencies, such as the lack of a Quality Management Plan, lapses in performance or review of quality control or proficiency testing, or implementation of a new procedure, cannot be corrected on-site. When a change to a process, policy or procedure requires additional training or retraining of personnel, the deficiency cannot be corrected on-site. In all cases, the inspector must indicate on the deficiency form how the deficiency was corrected.

Deficiencies corrected on-site during the inspection ARE deficiencies and will remain in the laboratory record. A laboratory response to the LAP with documentation of correction is not routinely expected, but for Phase II deficiencies corrected on-site, both a corrective action plan and evidence to support that the plan has been implemented may be requested as additional documentation post-inspection. The CAP reserves the right to request documentation from the laboratory concerning how a deficiency was corrected on-site

Deficiency Response Review

Upon return of the inspection packet from the inspection team leader to the CAP office, an audit of the packet and review of the ISR is performed by the laboratory accreditation staff to ensure that the material is complete. All deficiency responses and documentation of corrective action from the laboratory are thoroughly reviewed.

The inspection report is then forwarded to the Regional Commissioner. If the responses adequately address the deficiencies, the Regional Commissioner will notify the laboratory that accreditation is recommended.

Accreditation

The decision to accredit a laboratory is made by the Regional Commissioner when the laboratory has provided acceptable documented responses to Phase I and Phase II deficiencies, and satisfactorily documented correction of all Phase II deficiencies.

Upon recommendation of accreditation:

- The official accreditation letter is sent from the College to the laboratory director, with copies to the administration where applicable.
- The laboratory will receive a press release and a final list of deficiencies.

Accreditation is valid for two years from the date of the first inspection and is renewable every two years on the accreditation anniversary date. However, if the accreditation decision process goes beyond the accreditation anniversary date, the laboratory's accreditation is maintained in its current state until that decision is made. During this period, in situations where the laboratory is requested to demonstrate continuing accreditation, a letter may be requested from the LAP that verifies its accreditation status.

The laboratory should **keep the final list of deficiencies on record for review by other accrediting agencies** (e.g., The Joint Commission). A copy of the list of deficiencies is included in the next inspection packet.

Immediate Review Criteria

Immediate review criteria flag a laboratory's record for expedited processing by LAP staff and the Regional Commissioner. This occurs when a laboratory is cited with more than 2.5% of the total possible Phase II deficiencies and/or when a directorship issue is cited by the inspector.

In the past, laboratories with such large numbers of deficiencies have had difficulty correcting them within the allotted time. Following the review of these laboratories, the Regional Commissioners take such actions as:

- Direct communication between the director and Commissioner to determine whether correction is probable
- Order a focused reinspection of the problem areas.
- Recommend probation, suspension, or denial of accreditation.

Probation or Suspension of Accreditation

The Commission on Laboratory Accreditation, or the Executive Committee of the Commission, may place a laboratory on probation or any section of a laboratory on suspension. During probation, a cited laboratory or section is allowed to provide testing as an accredited laboratory. A suspended section is not allowed to provide accredited testing. When a probation or suspension decision is made, any agencies accepting CAP accreditation, including but not limited to the Centers for Medicare and Medicaid Services or the Joint Commission on Accreditation of Healthcare Organizations, will be notified.

Probation may occur for conditions that do not appear to pose a substantial risk of harm to patients or to laboratory personnel; for instance:

1. Facts surrounding the decision to accredit are unclear.
2. The Commission wishes to monitor the progress of the deficiency correction.
3. Laboratory conduct is contrary to the policy of the Commission.
4. The Commission has denied or suspended the accreditation of specific sections of a laboratory.

Suspension may occur if either of the following conditions is present:

1. The laboratory has deficiencies that may pose a substantial risk of harm to patients or to laboratory personnel, and the Commission either:
    a. Needs time to evaluate the situation further, or

   b. Concludes that the deficiencies can be corrected within a specified period.
2. The laboratory has failed to enroll in an approved proficiency testing program or has failed to meet proficiency testing performance criteria.

Full accreditation will not occur until the Commission determines that the deficiencies have been satisfactorily corrected. If a laboratory fails to correct these within a period deemed reasonable by the Commission, accreditation will be revoked and appropriate oversight agencies will be notified.

Denial or Revocation of Accreditation

Accreditation is denied or revoked when the laboratory fails to meet the *Standards for Laboratory Accreditation* or any other requirement for continued participation in the Laboratory Accreditation Program. The checklists represent the requirements for meeting the *Standards for Laboratory Accreditation*, and failure to correct cited deficiencies can be the basis for determining that a laboratory does not meet the intention of the *Standards*.

Laboratories with numerous deficiencies that cannot be corrected within a reasonable period may be presented to the Commission on Laboratory Accreditation for an accreditation decision. If conditions warrant, new laboratories trying to achieve accreditation for the first time may be advised to withdraw and reapply later.

Laboratories formally denied accreditation will receive notification by certified mail. Any agencies accepting CAP accreditation, including but not limited to the Centers for Medicare and Medicaid Services or the Joint Commission on Accreditation of Healthcare Organizations, will be notified.

Appeals

The laboratory may appeal the decision of denial or revocation within 30 days of receiving documented notice of denial. A request for reconsideration shall not stay the denial of accreditation. Request for information regarding appeal procedures should be directed to the Regulatory Analyst in the office at 800-323-4040, extension 7471, or 847-832-7471.

For additional detailed information concerning Accreditation probation, suspension, denial, revocation, and appeals, see: Excerpts of the Commission on Laboratory Accreditation Policy Manual (see page 141).

Post-inspection Critique

Upon receipt of the Inspector's Summation Report from the team leader, the College sends the laboratory director a post-inspection critique questionnaire. This questionnaire serves as an on-going quality assurance tool for the inspection process and is used to make continuous improvements at every level. The director and staff are encouraged to complete this form and provide comments and suggestions.

MAINTAINING ACCREDITATION

Terms of Accreditation

A CAP-accredited laboratory is obligated to:

- Notify the CAP office whenever the laboratory finds itself the subject of an investigation or inspection by a state or federal agency or adverse media attention related to laboratory performance.
- Have a written policy and procedure for investigating complaints from laboratory or other institutional employees and patients related to laboratory quality, performance, or accreditation. Incorporate investigation procedures and results into the laboratory Quality Management Plan.
- Provide an inspection team of a size and composition similar to that required for its own inspection, and perform at least one inspection during the two-year accreditation cycle, if requested by the Commissioner.
- Effectively participate annually in the CAP Surveys or a CAP-accepted alternative proficiency testing program. If the laboratory fails to meet the requirements of the LAP, the College may ask the laboratory to cease testing of the analyte(s) for a minimum of two proficiency testing events or until the laboratory can demonstrate acceptable performance in proficiency testing. If the laboratory refuses to cease testing, its accreditation will be in jeopardy.
- Notify the CAP office in writing of changes in location, ownership, or directorship of the laboratory. Accreditation does not automatically survive such changes. Documentation, including a copy of the new director's curriculum vitae (please remove the social security number) and an organizational chart, will be requested for evaluation of the accreditation status.
- Notify the CAP office when there is a change in the laboratory's test menu, prior to beginning that testing.**
- Authorize the CAP to release the laboratory's inspection and proficiency testing data to appropriate regulatory and oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, JCAHO, HFAP(AOA), and/or state agencies.

**Changes in test menu can affect checklist usage or the selected questions included in the laboratory's customized checklist. It is imperative that the laboratory notify the CAP as soon as its test menu changes. To assist this effort, a Test Menu Change Form is included in the materials sent to the laboratory at the reapplication and self-evaluation periods of the accreditation cycle. The form is also available at the CAP Web site and on the CD-ROM.

Proficiency Testing Participation

The laboratory must participate in a CAP-accepted PT program for all analytes designated by CAP (the list of these analytes is available at the CAP Web site). The CAP does not accept all CMS-approved PT Programs. Please contact your provider to verify CAP acceptance. The Laboratory Accreditation Program (LAP) will send a "non-participation" Proficiency Testing Exception Summary (PTES) if there is no PT score. The laboratory has three weeks to respond to any exception. It must identify the cause of the exception and describe the action it has taken to correct the problem and prevent recurrence of the issue. In your non-participation PTES packet, you will find helpful materials that describe why the PTES may have occurred, along with suggestions as to how to respond. Blank PTES response forms (included in the packet) are also available at the CAP Web site.

For those analytes for which CAP does not require CAP-accepted PT, the inspector will verify that the laboratory is using some other means to assess performance. The laboratory must check the accuracy of all of its tests at least semi-annually. Alternative assessment methods include the use of:

- Proficiency testing programs that are not specifically required; or
- PT programs designed as educational tools; or
- Split sample analysis with reference or other laboratories; or
- Split samples with an established in-house method; or
- Assayed material or regional pools; or
- Clinical validation by chart review; or
- Other suitable and documented means.

It is the responsibility of the laboratory director to define such alternative assessment procedures in accordance with good clinical and scientific laboratory practice.

Proficiency Testing Performance

The LAP monitors proficiency testing (PT) scores from all CAP-accepted PT programs for laboratories accredited by the LAP. This monitoring is performed approximately seven to 10 days after the PT program evaluates the results. The LAP compares individual laboratory PT scores to established criteria of acceptability. If the performance of an analyte or subspecialty falls below the acceptable criteria, a proficiency testing exception summary (PTES) packet of information is sent to the laboratory. For PTESs that do not require a response, which includes first time PT exceptions for any analyte, the inspector will review the documentation of the investigation and corrective action during the on-site inspection. Blank PTES response forms are also available at the CAP Web site.

The laboratory should investigate each unacceptable PT result, and document both the investigation and the specific corrective action taken to prevent recurrence of the problem. For those results that were not graded (identified by an non-graded reason code), please refer to Appendix I for appropriate action (see page 129).

Exceptions that consist of repeated failures (unsuccessful or repeat unsuccessful) for all analytes require a response. The laboratory must respond within three weeks to any such exception, identifying the cause of the exception and describing and documenting the action taken to correct the exception.

LAP staff will review the laboratory's PTES response. The LAP will request additional documentation if the response is incomplete. This request for additional documentation includes a response due date and

requires a written response. LAP staff may also provide informational letters suggesting changes to the laboratory's current testing processes for the analyte or subspecialty in question. A participant response is not required for these informational letters.

The LAP not only tracks unacceptable performance of an analyte or subspecialty for the current testing event, but it also tracks trends of unacceptable performance of PT scores from previous testing events. When PT performance is unacceptable for multiple testing events, the laboratory should provide documentation encompassing all of the unacceptable testing events and make note of the presence or absence of trends. Recurrent PT failures are considered especially critical. The laboratory's responses and corrective actions to recurring failures (repeat unsuccessful) are thoroughly examined. Reinspection and/or sanctions to the laboratory's accreditation may result.

To assist its on-site inspectors, the LAP includes a report of PT performance variances in the Inspector's Inspection Packet. This report flags every occurrence of an unacceptable result since the last inspection. The inspector will review records of calibration frequency, quality control results, validation of the analytical measurement range, and troubleshooting logs from the time periods for every PT variance.

e-LAB Solutions™: Laboratories using CAP Surveys can submit PT results online and view their scores online using e-*LAB* Solutions. Accredited laboratories may view a report that lists analytes with PT scores of less than 100% (PT exceptions that require follow-up.) With this report, a laboratory can easily track its PT exceptions directly online. If a response to the CAP is required, the laboratory can download a pre-populated response form, complete its performance investigation on a real-time basis, and fax documented corrective action to the CAP for efficient resolution of any PT issues.

Self-evaluation

At the beginning of the **second year of the two-year accreditation cycle**, laboratories complete a **mandatory self-evaluation,** using the checklists that are sent to the laboratory for this purpose. It is likely that the checklist version sent for use in the self-evaluation will be different from the version used for the previous or next on-site inspections. The self-evaluation verification form must be returned within 30 calendar days of receiving the self-evaluation materials. After conducting a self-inspection, the laboratory must complete the form, obtain the director's signature, and return it to the CAP. The verification form states that the laboratory will correct all deficiencies cited and that documentation of corrective action will be kept on file for review by the next CAP inspection team, which will observe to see if all deficiencies noted on the self-evaluation have been corrected. Deficiencies should be corrected within 30 days of the self-evaluation as are deficiencies cited by an on-site inspection team. The laboratory should keep the self-evaluation checklists on file for future reference. Failure to perform the self-evaluation is a serious deficiency and may result in an immediate on-site inspection or denial of accreditation.

Anniversary of Accreditation

Accreditation is maintained on a continuous basis provided that the laboratory continues to meet the Conditions of Accreditation. The LAP functions on a fixed accreditation cycle. This means that a laboratory will be **inspected every two years within the six-month period prior to the accreditation anniversary date.**

Implications of Accreditation/Recognition by Accrediting Organizations and Other Government Agencies

Certain regulatory agencies and other accrediting programs officially recognize the value of the CAP Laboratory Accreditation Program. All inspection data are confidential unless released by the director. The choice is voluntary. The director however has the option at the time of application to request that the results of the inspection be shared with the JCAHO or with selected governmental agencies. The regulatory and accrediting agencies that may receive copies of the inspection are listed in the following section.

The Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations [JCAHO])

Hospitals seeking Joint Commission accreditation may choose to accredit the hospital laboratory through the CAP program. The Joint Commission accepts CAP accreditation of hospital laboratories. Generally, a Joint Commission laboratory surveyor will not survey CAP-accredited laboratories in Joint Commission-accredited hospitals. During the hospital's survey, however, an administrative surveyor will examine laboratory safety and a physician surveyor will request and review information on the performance improvement activities of the laboratory and its medical staff. The Joint Commission will occasionally validate the CAP inspection process by sending an observer along with a CAP inspection team.

Centers for Medicare and Medicaid Services (CMS)

The LAP has been approved as a private accrediting organization under CLIA ’88 by the CMS. Therefore, CAP-accredited laboratories may use their CAP inspection in lieu of routine inspection by a CMS agent. This recognition imposes significant obligations upon the LAP. The fixed accreditation cycle must be honored by ensuring that laboratories are inspected within the 30 days prior to the laboratory’s accreditation anniversary date. In addition, CLIA ’88 requirements have been incorporated into the inspection checklists. Within each facility, CLIA certificates and CAP accreditation data must be concordant, (i.e., one CLIA number corresponds to one CAP number). CMS validates the CAP inspection process by sending surveyors to up to 5% of accredited laboratories, unannounced, within 90 days of completion of CAP inspections. Some validation inspections are conducted simultaneously with CAP inspections.

State Licensure

Some states license clinical laboratories. The extent to which the CAP accreditation program is recognized by state governments varies. The College will make the results of the accreditation decision available to a state agency upon request from the laboratory director.

The inspector can determine the accreditation implications of the current inspection by reviewing the "Release of Data" form in the packet. The director's signature on the form will indicate which agencies the laboratory has designated to receive CAP accreditation information.

NON-ROUTINE INSPECTIONS

The Regional Commissioner may request an on-site inspection outside of the routine accreditation cycle. The inspection may be announced or unannounced. For announced non-routine inspections, a letter explaining the process and a request for the inspection fee will be sent to the laboratory director. The laboratory and the individual performing the non-routine inspection will receive checklists for the laboratory section(s) being reinspected.

The Inspector's Summation Report (ISR) will indicate the time allowed the laboratory to respond to any deficiencies found during this out-of-cycle inspection. The technical specialist and the Regional Commissioner will review the deficiency responses in the usual manner.

Non-routine inspections may occur under the following circumstances:

Change in Location, Director, or Ownership

Accreditation by the CAP does not automatically continue after there is a **change in location, director, or ownership.** When such a change occurs, the CAP must be notified in writing within 30 calendar days in order to satisfy CLIA '88 requirements. Additional information may be requested from the laboratory.

After reviewing the case, the Regional Commissioner may find that no substantive changes in the operation of the laboratory have been made and that all the requirements of the *Standards for Laboratory Accreditation* are met. In these circumstances, the commissioner may waive reinspection and shall notify the College in writing of his or her recommendation. The laboratory will retain its accreditation until the next regularly scheduled inspection. An additional inspection, however, may be conducted at the discretion of the Regional Commissioner. A fee is assessed for this type of inspection.

Added Discipline

An "added discipline inspection" occurs outside of the regular inspection cycle and is used routinely for labs that **add anatomic pathology and/or cytology** testing. The addition of any other discipline may also require an inspection, at the discretion of the Regional Commissioner. A fee is always assessed for this type of inspection.

If the laboratory **adds a clinical pathology discipline** (e.g., toxicology, cytogenetics), additional application materials, a self-evaluation verification form, and a copy of the checklist for that discipline will be sent. When returned, these materials will be forwarded to the Regional Commissioner for review. After reviewing these materials, the Regional Commissioner will determine if this laboratory section requires an inspection before its next scheduled on-site inspection. If the section does not require inspection, a revised accreditation letter will automatically be sent after the Regional Commissioner's review. In this case, no additional fee is involved.

Secondary On-site Inspection

This inspection occurs within the regular inspection cycle and is conducted **after an on-site inspection**. The Regional Commissioner requests a second visit by a specialized team of inspectors to document correction of selected deficiencies in a specific discipline. This may occur if the laboratory failed to report all testing activities and therefore not all testing was inspected. A secondary inspection may also take

place when the deficiencies cited are so profound that the Regional Commissioner judges paper documentation of deficiency correction inadequate. A fee is assessed unless the reason for the inspection is due to an error on the part of the CAP (e.g., inspector missed the section, or the appropriate checklist was not supplied to the inspector).

Complaints

A complaint is the notification of the Laboratory Accreditation Program by an external source or through discovery of information outside the routine inspection process that alleges non-compliance with the Standards for Laboratory Accreditation.

The Complaint Process

As soon as the College receives a complaint, the complaint process is initiated. Depending upon the nature of the complaint, the investigation can include a request for information from the lab, a search of past inspection and proficiency testing results, or even an unannounced on-site inspection.

This inspection usually follows the same process as a secondary on-site inspection and can take place at any time during the accreditation cycle. The Special Commissioner for Non-Routine Processes will request this inspection when there is evidence of non-compliance with the *Standards of Laboratory Accreditation* in a currently accredited laboratory. LAP staff and the Regional Commissioner will review the response. Fee assessment is determined on a case-by-case basis. Alternatively, complaint investigations may be conducted as part of a routine on-site inspection if the timing is appropriate.

Based on the findings of that investigation, the CAP Laboratory Accreditation Complaints Committee will review the findings of the investigation and determine both the validity of the complaint and the appropriate course of action. The CAP recognizes that no two laboratories are exactly alike. Therefore, the course of action decided upon by the committee is tailored specifically to address any problems discovered during the investigation. All accreditation decisions are made by the CAP on a case-by-case basis. In addition, all substantiated complaints, plans of correction, and/or changes in accreditation status will be shared with state and federal accreditation agencies.

Proficiency Testing Exception Summary (PTES), Non-routine Inspection

This inspection usually follows the same process as a complaint investigation or secondary on-site inspection and can take place at any time during the accreditation cycle. The Continuous Compliance Committee (CCC) of the Commission on Laboratory Accreditation will request this inspection when there is evidence of repeated non-compliance with proficiency testing performance standards. LAP staff and the CCC will review the response. A fee is assessed for this inspection.

Appendix A:
CAP Checklist Usage

This appendix does NOT include all possible uses for a particular checklist. To verify checklist usage, contact the Laboratory Accreditation Program at 800-323-4040, extension 6065.

Laboratory General — Used to inspect **all** areas of the laboratory for quality management, specimen collection, results reporting, computer services, personnel, space, and safety.

Anatomic Pathology — Used for all surgical pathology, including frozen sections, histology/histopathology, autopsies, and electron microscopy. The Anatomic Pathology Checklist can also be used to inspect laboratories performing FISH (e.g., HER2) and ISH (e.g., HPV) techniques in histologic sections. The usage of this checklist for inspection of ISH techniques is limited to FDA approved kits only. Laboratories that only accession specimens should not use this checklist.

Chemistry and Toxicology — The Chemistry and Toxicology Checklist is used for:

- common chemistry tests typically performed on automated and semi-automated instruments;
- toxicology testing, including all screening and/or confirmatory testing for drugs of abuse, legal alcohol analysis, and other toxicology tests, regardless of methodology;
- blood gas analysis and oximetry;
- assays performed by flame photometers, atomic absorption, spectrophotometers, immunoassays, including enzyme immunoassays (EIA) and radioimmunoassays (RIA), GC/MS, TLC, HPLC, and electrophoresis;
- therapeutic drug monitoring (TDM), prenatal screening for fetal anomalies, abnormal hemoglobin detection, and cystic fibrosis screening.

Cytogenetics — Used for amniotic fluid cell analyses, bone marrow cultures, chorionic villus studies, Fragile X studies, blood lymphocyte analyses, solid tumors, and non-neoplastic tissue cultures. Biochemical genetics testing (e.g., amino acids analysis) will be inspected with the Chemistry and Toxicology Checklist.

Cytopathology — Used for all (gynecologic and non-gynecologic) cytopathology, including processing, screening, pathologist evaluation, liquid-based methods, and automated screening instruments. Laboratories that only accession specimens should not use this checklist.

Diagnostic Immunology & Syphilis Serology — Used for non-syphilis serology testing such as hemagglutination, immunoassay, immunofluorescence, direct antigen detection, and for syphilis testing by fluorescent and/or serologic methods.

Flow Cytometry — Used to evaluate flow cytometry assays, including DNA analysis, lymphocyte phenotyping, leukemia/lymphoma immunophenotyping, and CD34 stem cell enumeration.

Hematology and Coagulation — Used for blood cell counts and differentials, coagulation testing, bone marrow analysis, body fluid analysis, examination of blood films for malaria and other parasites, and abnormal hemoglobin detection.

Histocompatibility — Used for all transplant tissue compatibility (HLA) studies, including HLA typing, crossmatching, HLA antibody screening and identification, and mixed lymphocyte culture testing. The Histocompatibility Checklist is used to inspect HLA testing performed by serological, immunoassay, flow cytometry, and molecular pathology methodologies.

Limited Service Laboratory — Used for freestanding laboratories or a section of a laboratory doing a limited number of basic tests in multiple disciplines (e.g., outpatient or "STAT" labs). This checklist is not appropriate for single-discipline or specialized laboratories; these laboratories must use the appropriate discipline-specific checklist(s).

The Limited Service Checklist does NOT cover the following services:

- Hematology — bone marrow evaluation, blood film examination for malaria, and abnormal hemoglobin detection (except the sickling test).
- Coagulation — factor assays, mixing studies, and platelet function testing.
- Chemistry — toxicology (*other than drug of abuse screening for medical purposes and serum or whole blood medical alcohol),* spectrophotometry, electrophoresis, chromatography, AFP, RIA, and sweat testing for cystic fibrosis.
- Microbiology — cultures beyond initial plating, mycology other than KOH or wet preps, mycobacteriology, parasitology other than pinworm preparations and virology, and molecular microbiology, including DNA testing using amplified and non-amplified methods. Limited Service may be used for direct antigen testing for all Microbiology subdisciplines.
- Transfusion Medicine — any testing other than ABO/Rh and antibody screening (non-transfusion), and direct antiglobulin testing.
- Separate discipline-specific checklists are required for: Anatomic Pathology, Cytopathology, Cytogenetics, Histocompatibility, Flow Cytometry, Molecular Pathology, and Point-of-Care-Testing.

Microbiology — Used for bacteriology, mycobacteriology, mycology, parasitology, and/or virology, and molecular microbiology. Microbiology laboratories performing unmodified FDA-approved molecular tests, excluding quantitative methods such as viral load testing, may use the Microbiology Checklist alone. Methods that are not FDA-approved (or FDA-approved methods that have been modified by the laboratory) require the Molecular Pathology Checklist. A current listing of FDA-approved tests can be found on the Association for Molecular Pathology (AMP) Web site at www.ampweb.org.

Molecular Pathology — Used for molecular techniques for oncology, genetics, parentage, forensic identity, and *in situ* testing.

Point-of-Care-Testing — Used for Point-of-Care-Testing (POCT) performed in non-dedicated space (i.e., with portable instrumentation). A discipline-specific checklist(s) may be required in addition to the Point-of-Care-Testing Checklist if certain analytes performed in non-dedicated space warrant its use. Dedicated laboratories require either a Limited Service or additional discipline-specific checklist(s). A separate checklist must be completed for each POCT location when POCT records are not maintained in a central location. The Point of Care Checklist is used to inspect Physician-performed Testing that is under the responsibility of the laboratory director.

Team Leader Assessment of Director & Quality — Used by the inspection team leader to evaluate the laboratory director and provide an overall evaluation of the quality management program of the laboratory.

Transfusion Medicine — Used for blood, blood component, tissue storage, compatibility testing, transfusion services, donor collection, component preparation, bone marrow and/or progenitor cell services, and blood group parentage testing. Laboratories with immunohematology testing limited to ABO, Rh, antibody screens (non-transfusion), and direct antiglobulin testing may be inspected with the Diagnostic Immunology & Syphilis Serology Checklist.

Urinalysis — Used for automated and semi-automated urinalysis, dipsticks and dipstick readers, morphology systems, and microscopic urinalysis.

Appendix B:
Guidelines for Determining Test Volume

Test volumes are requested for each laboratory section and are separated into the following categories:

CMS-reported — Includes test volumes for all high and moderate complexity testing performed in each section. This information is reported to CMS annually. Do not include calculations (e.g., A/G ratio, MCH, base excess, anion gap, iron saturation, INR), quality control, quality assurance, and proficiency testing assays.

CMS-non-reported — Includes test volumes for waived testing and other tests or procedures to be inspected that are not classified by CMS (e.g., autopsy, in-line testing, employee drug testing) for each section. These totals are used for on-site inspection planning only.

Specialty information:

Chemistry: For profiles, each individual analyte is counted separately.
Cytogenetics: The number of tests is determined by the number of specimen types processed on each patient, (i.e., a bone marrow and a venous blood specimen received on one patient is counted as two tests).
Cytology: For CMS statistics, each slide (not case) is counted as one test for both Pap smears and non-gynecologic cytology. At the time of application/reapplication, LAP also requests the number of surgical/cytology accessions to better indicate to the inspector the size and scope of these laboratory services.
Hematology: For complete blood counts (CBCs), each *measured* individual analyte ordered and reported is counted separately. Differentials count as one test.
Histocompatibility: Each HLA typing (including disease-associated antigens), HLA antibody screen, and HLA crossmatch is counted as one test.
Histopathology: For CMS statistics, each block (not slide) is counted as one test. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory. At the time of application/reapplication, LAP also requests the number of surgical/cytology accessions to better indicate to the inspector the size and scope of these laboratory services.
Immunohematology: Each ABO, Rh, antibody screen, crossmatch, or antibody identification is counted as one test.
Immunology: Testing for allergens should be counted as one test per individual allergen.
Microbiology: Susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification.
Urinalysis: A microscopic examination is counted as one test. A macroscopic (dipstick) examination is counted as one test, regardless of the number of reagent pads on the strip.

Appendix C:
Unannounced Inspection: Tips for Laboratories and Inspectors

Tips for Laboratories

Prior to the Inspection

1. Notify relevant hospital medical and administrative personnel of the change to unannounced inspections (a template letter is available at www.cap.org; Laboratory Accreditation; Resources for Labs). Ask for their support as well as contact information for primary and backup individuals who need to be notified on the day of the inspection and who would be available for interviews by the inspection team.

2. Identify primary and back-up staff for each area of the lab who will have knowledge of procedures, policies, and location of key documents (e.g., QC, PT, QM, training and competency, instrument validation, AMR records).

3. Identify inspection day tasks and assign primary and backup staff for each task (see sample task list).

4. Develop a phone list of primary and backup staff to contact upon the arrival of the inspection team. List should include CEO, medical chief-of-staff, medical director, lab director, lab manager and section head supervisors. If the lab needs additional FTEs on the day of the inspection, a list of employees who have previously indicated the ability to work on short notice should also be available.

5. For each Checklist question, note the location of documents or records that demonstrate compliance to the requirement. This may be a good opportunity to have department staff review the questions and attach samples of records or forms as appropriate.

6. Develop a process for timely retrieval of off-site records, such as personnel training records and initial instrument/method validation studies. Store on-site documents and records in a central location so that they are easily accessible during the inspection. Ensure that relevant staff knows how to locate or retrieve the documents and records.

7. Identify options for workspace that can be used by the team. Space can either be in the laboratory, in an area designated for clerical/administrative services, or elsewhere in the institution that is convenient to the lab.

8. If the inspection team has to travel from site to site, develop maps and identify possible modes of transportation in case the team has not previously made travel arrangements.

9. Train all staff so that they are familiar with the Checklists and the inspection process. Show the video that is included with the reapplication process to reinforce the general CAP approach to inspections and familiarize staff on what to expect. Unannounced inspections could be an ongoing agenda item at lab meetings to increase communication and provide preparedness updates.

Inspection Day

1. Activate the inspection day task list and refer to it as necessary during the day.

Post-Inspection

1. Identify successes and develop an action plan for what you might do differently for your next inspection.

2. Make appropriate changes as soon as feasible.

3. Use the self-evaluation period to refine your inspection day processes. Have a group of staff (preferably your designated inspection back-up staff) conduct an unannounced inspection of the lab or section of the lab. This will help you spot areas that you may have overlooked or that need better clarification, and will give your back-up staff the experience of having primary staff explain how the laboratory is in compliance.

4. Continue to communicate with staff, conduct drills, and evaluate the process throughout the two years.

SAMPLE INSPECTION DAY TASKS

Task/Role	Primary Staff/ Extension #	Backup Staff/ Extension #
Designated central contact for the inspection		
1. Secure workspace for the inspection team		
2. Greet the inspection team at the reception desk and lead them into the lab or to the workspace		
3. Assess workflow/FTE situation; make appropriate modifications as necessary		
4. Make appropriate phone calls to notify that inspection team has arrived		
5. Schedule interviews with CEO and Chief-of-Staff		
6. Arrange for food and beverages – coffee/water/drinks and lunch		
7. Arrange for off-site records to be delivered		

ADDITIONAL INFORMATION

- Please note that the Checklist edition sent with your reapplication will be the edition used for your inspection. The Checklists will be customized. For answers to other Frequently Asked Questions, visit the CAP Web site.
- Taped audioconferences provide more information about unannounced inspections and are available on the CAP Web site at www.cap.org.

Tips for Inspectors

Prior to the Inspection

1. Communicate with CAP staff to coordinate the inspection. Staff can help clarify any questions that you may have about the inspection and can also help identify additional team members if needed, particularly if a specialty inspector is required for the inspection.

2. Review the Inspector's Packet and plan the inspection – allow sufficient time for the inspection especially in light of the new unannounced inspection process. Consider planning to arrive one hour earlier than usual to allow the laboratory a little extra time.

3. When scheduling the inspection day, consider the laboratory's operating hours and any other applicable holidays (like federal or Canadian). Choose a day when the lab is operating at its fullest capacity, typically on a weekday. By doing so, you will be able to assess most, if not all, aspects of lab operations and will likely encounter the appropriate staff that you will need to interview and observe. Be sure to schedule around the laboratory's indicated black out dates.

4. If the laboratory that you are inspecting requires security clearance, allow for an extra half hour in the morning for any clearance details to be worked out on-site.

5. Meet with your team:
   - Distribute appropriate lab information to each inspector on the team.
   - Inform team members to bring identification.
   - Remind team members to be flexible and to keep the inspection moving; if a document is not readily available, an inspector should move to another part of the Checklist until the lab has located the appropriate documentation.
   - Remind team members to interview lab staff and observe testing to make sure written policies and procedures match actual practice.

6. Ensure that your team members are trained; Web-based sessions are available at www.cap.org under the Education tab.

Inspection Day

1. Meet team members at a central location away from the laboratory. Arrive at the laboratory as a group.

2. Assume that breakfast will not be provided by the lab because they are not expecting you. Make your own plans for this meal and arrive at the lab ready to inspect.

3. Present the letter that identifies your team as a group representing the CAP to the lab; wait until the lab verifies the information. Ensure that all team members can provide personal identification if asked.

4. Be courteous and patient as the lab organizes its day – it may take them a while to institute their action plan.

5. Meet with your team members throughout the day; keep lines of communication open to ensure that the inspection is proceeding according to plan. Ensure that any deficiencies are discussed with the laboratory as identified throughout the day.

Post-Inspection

1. Identify successes and develop an action plan for what you might do differently for the next inspection.

2. Make appropriate changes and evaluate the process with your team members.

Appendix D:
Sample of Inspection Confirmation Letter to Laboratory Director

Use this letter for announced inspections only. The template letter should be customized and sent by the team leader to the Director of EACH laboratory to be inspected, including separately accredited blood gas or special function laboratories. **The team leader should also place a copy of the customized letter in the inspection packet.**

An electronic template of this letter is available at on the CD "Your Inspection Resource," which is included in the laboratory and inspector packets.

Dear Dr. (...):

This letter is to confirm our telephone conversation in which we arranged the CAP inspection of your laboratory. We plan to arrive at your laboratory on (...) at about (...) and anticipate that the inspection will last approximately (...).

Assisting me in this inspection will be the following individuals and the areas they will inspect:
(Insert as applicable e.g., Laboratory General: (name of inspector)
Hematology: (name of inspector)
Chemistry: (Name of inspector)……

We would like to meet with you and your staff briefly at the beginning of the visit to review the day's schedule and to take a brief walking tour of the laboratory. Team members will then go with the respective supervisors to inspect the departments. If possible, please provide a workspace in an office or conference room.

(Insert the paragraph below for hospital laboratories)
Please arrange for brief appointments of 15 minutes each with the hospital administrator and a representative of the medical staff. These meetings help determine whether the laboratory has established an effective working relationship with the administration and staff. Ideally, these meetings should take place about halfway through the inspection.

The inspection will proceed more efficiently if the laboratory has those items of special interest readily available. As we go through the checklists, we will review the following:

1. **Laboratory General**
   a. Personnel policies and complete personnel records (gathered and organized at one site that is convenient to the laboratory)
   b. Quality management plan and records of meetings, studies, etc.
   c. Continuing education records
   d. Self-evaluation records from last year
   e. A copy of those portions of the hospital nursing manual or doctor office directions that relate to specimen collection and to transfusion of blood
   f. Professional qualifications of all section (general) supervisors; readily available in one location for the inspector
   g. Chemical hygiene plan and annual evaluation of plan
   h. List of all laboratories to which you refer specimens, along with their CLIA numbers

i. Validation records (method performance specifications) for all analytes currently being tested

2. Each department

a. Procedure manuals
b. Instrument maintenance records
c. Quality control and proficiency testing records
d. Safety manual
e. Examples of report forms

3. Hematology

Example slides of Romanowsky and reticulocyte stains

4. Microbiology

Example slides of Gram stain and other stains

5. Chemistry

Reference thermometers, reference weight standards, and volumetric glassware

6. Anatomic Pathology

Reports and slides for at least 10 surgical pathology cases, preferably of various complexities and types, five autopsies, and example slides of all routine and special stains offered

7. Cytopathology

Final reports and slides from approximately 15 cases (both gynecological and non-gynecological cases, positives and negatives, as applicable), as well as qualifications of all personnel, workload records, rescreening documentation, yearly statistics, and other quality management records

8. Cytogenetics

Examples of normal and abnormal cases for every test method

9. Molecular Pathology

A sampling of completed case records (five recently completed cases for each of the main types of analyses offered, both normal and abnormal if possible)

We expect to complete the inspection by (x:xx PM), at which time we would like to meet with you and your staff again for the summation conference to discuss the inspection findings. Please invite as many personnel from the laboratory to this meeting as you deem appropriate. We plan to adjourn by (x:xx PM).

(Include this sentence as appropriate.)
If you have any suggestions for luncheon arrangements, lodging, or travel directions, please let me know.

We look forward to meeting you and your staff on (. . .).

Sincerely,

_____

Team Leader's Name

Appendix E: Resources

CAP Web site (www.cap.org)

- To access the Laboratory Accreditation area of the CAP Web site at www.cap.org:
    - Select (click on) the folder at the top right hand area of the page titled "Accreditation and Laboratory Improvement"
    - Scroll down to the "Accreditation and Inspection Information" section

- Select the desired topic from the following options:
    - What's New
    - Inspection Checklists
    - Resources for Laboratories
    - Preparing to Inspect
    - Proficiency Testing Performance
    - Specialty Accreditation Programs
    - Applying for the Accreditation Program
    - Accredited Laboratory Directory
    - Laboratory Accreditation Newsletter

"Your Inspection Resource" CD-ROM

This resource contains most of the materials available at the CAP Web site, including the inspection checklists and commentaries and other helpful documents, forms, and templates related to the following topics:

- Checklists and Commentaries
- Accreditation Manual and *Standards*
- Proficiency Testing Documents
- Resources for Inspectors
- Resources for Laboratories: Application Request Form; various Change Forms; HIPAA Business Associate Agreement; Post-Inspection Documents; Information about Preparing for Inspection, Self-Evaluation Documents

This CD is routinely updated and mailed at the application, reapplication, and self-evaluation cycles of the accreditation process. It is also sent to the inspector and laboratory in their respective inspection packets. Call 800-323-4040, extension 7343, to request additional CDs.

Inspection Checklists

The inspection checklists are available at the CAP Web site at www.cap.org, where you can view and/or download the checklists currently in use as well as the previous edition. When a checklist is updated and a new version is posted, a red-line/strike-out checklist comparison document showing all the changes between the current and previous version is also made available at the Web site. If you do not have access to the Web site, please refer to the Inspection Resource CD sent with your application and self-evaluation materials, or call the Laboratory Accreditation Program to obtain a paper copy of the checklists.

Laboratory Accreditation Toll Free Telephone Line
LAP staff are available Monday through Friday from 8:00 AM to 5:00 PM Central Time at 800-323-4040. Select extension 6055 for assistance with all pre-inspection questions (application, reapplication, self-evaluation). Medical technologists answer technical questions and inquiries about the interpretation of checklist requirements before, during, and after the inspection (during the deficiency responses) via extension 6065.

The Laboratory Accreditation Program may also be reached at 847-832-7000.

Laboratory Accreditation e-mail Correspondence (accred@cap.org)
Inquiries sent via e-mail to accred@cap.org will be responded to within two business days.

LAP Inspector Training Opportunities
Live seminars, audioconferences, and online inspector education are available at no cost to participants. CME/CE credits/hours are offered for most. Please refer to the section in this manual, "Preparing for the Inspection: Training the Inspection Team Leader and Team Members," for more detailed information (see page 19).

Laboratory Inspection Preparedness Training
Several audioconferences are offered each year to assist laboratories in preparing for CAP inspection. Delivered directly to the laboratory at no cost to participants of the CAP Laboratory Accreditation Program, each audioconference provides a detailed examination of a topic. The sessions also include question and answer periods. CME/CE credit is offered. These are also available at the CAP Web site beginning approximately three weeks following each live presentation.

To register for any accreditation education event:

Online: Select the Education Programs folder; under "course catalog" select LAP Education Activities; follow the prompts
Phone: 800-323-4040, ext.7525, or 847-832-7525
Fax: 847-832-8006
E-mail: education@cap.org

CAP Surveys Program
The College of American Pathologists Surveys program started in the 1940s with distribution of a limited number of specimens to a few selected laboratories. Since then, the program has expanded to more than 500 proficiency testing surveys. The program is refined and updated annually to meet the changing needs of laboratory medicine. Today, more than 24,000 laboratories are enrolled in the CAP Surveys Program. e-LAB Solutions™ ensures streamlined data submission, improving the timeliness of evaluation data. The CAP Council on Scientific Affairs provides the scientific expertise for the program design and operation, with the assistance of 27 scientific resource committees. Nearly 400 practicing pathologists and consultants serve on these committees.

To assist laboratories in selecting CAP Surveys appropriate for their scope of operations, the CAP Surveys & Anatomic Pathology Education Programs catalog presents the available programs in discipline-specific sections.

Included in the Surveys catalog are:
- Customer support and ordering information
- Descriptions of individual programs

- Guidelines for selection of Surveys
- Indices by analytes/procedures, program name, and program code
- Explanations of opportunities for continuing education (CE credits) for selected surveys
- Shipping and pricing information

The EXCEL® Program
The External Comparative Evaluation for Laboratories (EXCEL) program is designed specifically for use by physicians' office laboratories or other laboratories performing only limited and routine procedures.

This proficiency testing program helps monitor the laboratory's internal quality control program by providing information on its performance and comparison of its procedures with other laboratories using the same or similar methods.

The flexible format allows subscribers to select EXCEL modules in chemistry, hematology, coagulation, urinalysis, microbiology, blood bank, and immunology. Specimens have been designed specifically for the scope of testing performed in physician office laboratories.

In addition, each individual may now receive up to 12 CE credits for participating in the education activities included with each mailing of EXCEL specimens. The education activity is designed to provide technical and non-technical information and consists of a related reading found in the Participant Summary and learning assessment questions available online at www.cap.org.

LAP News
This column is published several times each year in CAP TODAY by the College's Commission on Laboratory Accreditation to inform participants and inspectors of program changes and developments. It is the Laboratory Accreditation Program's official vehicle of notification of program changes to LAP participants.

CAP TODAY
This monthly periodical addresses the most current topics related to the practice of Laboratory Medicine. It is free to qualified laboratory professionals in the U.S. and Canada and available for $180 to international laboratories. An individual may renew or subscribe by completing one of the renewal requests that are bound to periodic issues throughout the year. If you do not receive *CAP TODAY* and would like to subscribe, log on to www.cap.org to complete a subscription form.

NewsPath®
NewsPath® is a series of articles written by pathologists and is available for pathologists to provide to their clinicians, increasing the visibility and understanding of pathologists' services. Overseen by the CAP Public Affairs Committee, *NewsPath* presents articles addressing concerns clinicians have about laboratory testing.

NewsPath has now transitioned into a free online-only publication available at www.cap.org and can be accessed under the References Resources and Publications folder at the home page. Articles are available in HTML, MS Word, and PDF formats for you to print, e-mail, or include in your own newsletters.

Feel free to download and use these *NewsPath* articles in other publications and presentations in your office, laboratory, and/or hospital to help spread the word about your practice and the important

contributions pathologists make to patient care. These articles are provided to you by the College as a service to the medical community and may be reproduced in whole or in part free of charge.

For additional information, contact the CAP at 800-323-4040, or newspath@cap.org.

CAP News
This periodical is available four times a year and provides information of new developments in accreditation. It is written for participants in the CAP Laboratory Accreditation, Surveys & Anatomic Pathology Education, EXCEL, and Quality Management Programs. It can be accessed from the CAP Web site home page under the References Resources and Publications folder. Ideas for new programs and other feedback can be sent to CAP by e-mail at labnews@cap.org.

CAP Publications
CAP Publications are a source of the latest in innovative texts, atlases, and other publications in the field of pathology. For more information or to order, call 800-323-4040, option 1, or visit www.cap.org and select the References Resources and Publications folder at the home page. Go to the CAP Web site to view the table of contents and a sample chapter for each of the publications below, which may be of particular value to CAP-accredited laboratories.

Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction, 2005 (formerly the *Quality Improvement Manual in Anatomic Pathology*).
Item Number: PUB118

This manual provides pathologists and lab directors with the tools necessary to develop, implement, and maintain a comprehensive quality improvement program. It emphasizes regulatory compliance, with cross-references to the CAP Laboratory Accreditation Program checklist items and CLIA regulations.

More than just a new edition, this Quality Manual has been expanded to include all-new sections in histology and immunohistochemistry, as well as a new section designed to address error reduction in surgical pathology. This manual also includes updated sections on cytopathology and autopsy pathology; comprehensive coverage of the pre-analytic, analytic, and post-analytic anatomic pathology test cycle; detailed benchmark data with extensive references; and information on diagnostic discrepancies and suggested actions. Helpful examples of forms to document quality assurance activities are included.

Quality Management in Clinical Laboratories: Promoting Patient Safety through Risk Reduction and Continuous Improvement, 2005
Item Number: PUB214

This is a practical “how-to” manual written for the laboratory director, supervisor, and practicing pathologist. Sponsored by the College of American Pathologists Quality Practices Committee and Patient Safety and Performance Measures Committee, the manual is designed to help readers manage quality and patient safety in clinical laboratories; comply with quality and patient safety regulations and accreditation requirements; and develop and administer a quality management plan.

Quality Management in Clinical Laboratories covers the most important standards and areas that have proven to be particularly problematic in the management of clinical laboratories. Patient safety issues—an essential and inseparable component of laboratory quality—are discussed throughout the text.

Contents include:

- Case studies based on knowledge of actual events
- Approaches to managing quality and patient safety
- Regulation and accreditation
- Specific quality and patient safety risks and control measures for pre-analytic, analytic, post-analytic, and general laboratory operations
- The laboratory quality management plan, with sample plans
- Extensive glossary and up-to-date references

Autopsy Performance & Reporting, Second Edition, 2003
Item Number: PUB114

This publication is intended for the pathologist who may not deal with autopsies on a regular basis. Topics covered include:

- Autopsy history, CAP documents pertaining to the autopsy, and concerns about the autopsy
- Autopsy safety, including high-risk cases and special precautions for Creutzfeldt-Jakob disease
- Autopsy performance, including maternal, placental, and perinatal/pediatric autopsies; organ and tissue procurement; and evaluation of transplant recipients
- Autopsy procedures for the CNS, special studies on the heart and lungs, and sampling for microorganisms
- Autopsy reporting, including medical certification of death and communication of autopsy results

Appendix F:
Site Coordinator's Manual

COLLEGE OF AMERICAN PATHOLOGISTS
LABORATORY ACCREDITATION PROGRAM
SITE COORDINATOR′S MANUAL

This information only applies to announced inspections.

INTRODUCTION

CAP inspections at a large facility are complex. Team leaders have found it helpful to have one local contact person with knowledge of all the laboratories to serve as Site Coordinator (SCO).

Many concerns must be addressed and decisions made before the inspection. Careful planning and attention to details on-site will make an inspection go smoothly. Considerations include the following:

1. How will the team get from its hotel to the laboratory on time and ready to inspect?

2. Do we know who the team members are and what sections each individual will inspect?

3. Are there other laboratories on the same campus that the team will be inspecting on this trip, and how will those inspections be scheduled?

4. Does the laboratory have satellite labs at other locations? How will the appropriate team members get there and return?

5. Are there any special services the team will need that the laboratory can supply to make the experience easier and more efficient?

Such questions cannot be addressed by the CAP office, or its travel agency, or perhaps not even by the team leadership. A local laboratory coordinator can be of immeasurable help in anticipating such issues and preventing complications or delays. This manual was developed for the Site Coordinator.

No document of this type can anticipate every organizational arrangement. CAP teams are often assigned to clusters of laboratories in one location to minimize travel costs. Many small laboratories may be spread throughout the campus and some of them may reside in departments other than pathology. The central laboratory may support multiple satellite laboratories; any that are within 15 miles or 30 minutes driving distance will be assigned to the team. Sometimes entire groups of partnering hospitals may be inspected at the same time. This document is meant to be a guideline—a set of suggestions that the Site Coordinator can adapt to her or his local situation.

The Commission on Laboratory Accreditation would like to gratefully acknowledge the following individuals who have assisted in the production of this manual by providing resource information and participating in review of draft copies:

- Beverly Charlton, University of Pittsburgh, Pittsburgh, Pennsylvania

- Terry Jo Gile, Barnes-Jewish Hospital, St. Louis, Missouri
- Dottie Quinn, Kaiser-Permanente Laboratories, Portland, Oregon
- Joyce Wilson, University of Alabama, Birmingham, Alabama

Their expertise and experience have made this Site Coordinator's manual possible. *Edits have been made periodically by the CAP staff to ensure accuracy.*

WHAT IS A SITE COORDINATOR (SCO)?

The site coordinator is the laboratory individual whom the director has appointed to work directly with the inspection team. The SCO works with the inspection team to convey their needs to the key people in the laboratory being inspected. The SCO also makes sure the team is aware of any special requirements the laboratory might have. During the inspection, the SCO should be available to the team to meet any last-minute needs. Site Coordinator duties typically include:

- Scheduling meeting rooms and lunch arrangements;
- Arranging key interviews;
- Coordinating inspection activities with supervisors and key staff;
- Assisting the team with travel logistics, (i.e., directions, advice on lodging, arrangements for satellite laboratories);
- Assisting the team with arranging for any special needs.

WHAT IS THE ROLE OF THE SITE COORDINATOR?

The role of Site Coordinator is not standardized. The campus arrangement and the team preferences will dictate tasks. The best way to list the duties of a SCO is to answer the question, "If I were organizing the team that will inspect our laboratories, what arrangements would I need?"

The SCO should be available to the team throughout the inspection. Even the best-planned inspections may need last minute arrangements. Flexibility is essential, especially on big, multidisciplinary campuses. The SCO helps resolve unanticipated situations as they arise. Experience has shown that the only role the SCO should have during the inspection is to be present and available to answer the team's questions.

IS A SITE COORDINATOR REQUIRED?

An inspection will benefit from a Site Coordinator if the answer is yes to any one of these questions:

- Does the inspection require a team of eight or more members?
- Will the inspection team travel from out-of-town and require overnight accommodations?
- Is there more than one location to be inspected?
- Are there two or more laboratories to be inspected at one location?

There is no requirement to have a SCO, but if the decision is made to do so, the SCO should be appointed as soon as the reapplication (mailed 150 days before the laboratory's accreditation anniversary date) arrives so the individual can begin the planning process.

HOW IS A SITE COORDINATOR APPOINTED?

Usually the director of the central pathology laboratory appoints the SCO regardless of whether the complex of laboratories is administratively related or laboratories are located in other departments. It is

not the College's intention to have the pathology department dominate the inspection but it is hoped that the entire inspection will proceed more successfully for everyone with one person in charge of coordination.

The Site Coordinator can be anyone who is willing to work with the team and with the laboratories, in advance, to plan for a smooth inspection. It will take several telephone calls, many hours, and attention to detail. With the right coordination and planning, an efficient, productive inspection will result that will be a positive experience for both the laboratory and the inspection team.

WHEN DO THE SITE COORDINATOR RESPONSIBILITIES BEGIN?

The SCO should begin work before the completed applications/reapplications are sent to the CAP office, so that he/she knows the content of the paperwork. The first step is to draw up a list of all laboratories that will be included in the inspection. Questions regarding inspector assignment can be answered by the calling LAP staff at 800 323-4040, extension 6055, or 847-832-7000, extension 6055. The CAP's list is only as accurate as the information available at the time of the call. Applications from special function, satellite, and affiliated labs may be accepted up to 30 days prior to the main clinical laboratory's accreditation anniversary date (or even later with the approval of the Regional Commissioner and team leader). Once the list is compiled, the SCO may identify acceptable dates for the inspection by contacting the directors of the other laboratories to determine their preferences. **The inspection must occur within the six-month window before the accreditation anniversary date of the main laboratory.** Offering more inspection date choices increases the likelihood that a mutually acceptable date will be selected. Potential conflicts such as vacation schedule, remodeling, and computer installations may be taken into consideration, but none of these can delay an inspection. The final selection of an inspection date will be at the convenience of the inspector. The Laboratory Accreditation Program (LAP) operates under the policy that a laboratory that is reporting results is always ready for an inspection.

REPORTING RELATIONSHIPS

Soon after appointment, the SCO should clarify her or his responsibilities to the facility for this inspection. Duties will vary by location and by the number of labs and their interrelationships. The chairman of the Pathology department should empower the SCO to handle as many of the details of the inspection as possible. Local arrangements can involve many telephone calls and some negotiation. There may be the need to make quick decisions during the inspection.

COMMUNICATION

Good communication is key to inspection planning. To be effective, the SCO should be knowledgeable about the team, the facility, and the schedule. Correspondence from CAP staff and the team leader is addressed to the laboratory directors or administrative contact person, if specified. The SCO should obtain copies of all pertinent correspondence. Any letters sent by the SCO to the CAP office or the inspection team should be copied to the appropriate laboratory directors.

The SCO will need the names of each of the team members as well as their credentials and areas of expertise. The managers and supervisors want to know exactly who will be in their laboratories. In addition, the inspection team members want to know which employees will be working with them during the inspection.

The SCO will assign a host for the inspector of each special function laboratory. The host would facilitate point-to-point communication and escort the inspector to their assigned area.

LOGISTICS OF SATELLITE LABORATORY INSPECTIONS

Satellite laboratories are off-site facilities that are administrative extensions of the main lab. Logistics of inspecting these laboratories include transportation for the team to and from the satellite lab, and the time allocated for this travel. There is no LAP requirement for the host laboratory to provide local ground transportation, but it is far simpler for the inspection team when the laboratory chooses to do so. In all cases, the inspection team needs to know in advance how it will get to and from each of the locations included in the inspection.

When a pathology laboratory supports multiple satellites, centralization of records and standardization of procedures are common. The SCO should describe the arrangement to the team well before the inspection. **If records are kept in a central location, copies of these records should be available to the inspection team at the satellite laboratory on inspection day.** Records to be reviewed include personnel files, employee health records, proficiency test evaluation reports, biomedical equipment maintenance records, and the Quality Management Plan.

HELPING WITH TRAVEL ARRANGEMENTS

For the inspection team: The CAP can assist the inspection team in meeting its travel needs. The CAP Travel Desk agents may be reached at 800-323-4040 or 847-832-7000, extension 7800, from 8 AM to 5 PM Central Time. Or you may fax 847-832-8800 or send e-mail to them at (captraveldesk@cap.org) 24 hours a day. **If air travel is required, all arrangements must be made through the CAP Travel Desk.** The seven-digit CAP number of the laboratory to be inspected must be given to the agent when booking travel. The College encourages early booking for favorable rates. If a team member needs to change his/her ticketing for the return trip, the CAP Travel Desk agents should be contacted as soon as possible.

The CAP Travel Desk agents can also arrange hotel accommodations and rental cars, if applicable. **Hotel reservations must be made through the CAP Travel Desk if more than 10 total hotel nights are being booked for the team.** With four to six weeks notice, the meeting-planning department at the College can negotiate a master account to cover the room rates and tax. Inside the U.S., insurance should be declined for rental cars. Outside the U.S., the inspector is encouraged to purchase the rental car insurance.

For the Site Coordinator: The SCO should suggest a list of nearby hotels. Team member costs for meals, ground transportation, and covered incidentals are reimbursed according to the standard CAP meeting policy.

The SCO should advise the team on the best way to get from the airport to the hotel. Most “chain” hotels offer free shuttles or can recommend low cost shuttle service. The SCO should suggest transportation arrangements for the team between the hotel and the lab. There is, of course, no requirement that the laboratory provide transportation, but any help the laboratory can offer the team will simplify the process and minimize its logistic decisions. With advance notice, the CAP travel desk agents can help arrange direct-billed ground transportation.

MEETINGS AND MEETING ROOMS

Every inspection team needs a home base. The SCO should ensure that the team has a work area for their use. Team members inspecting large campuses will fan out toward their individual assignments. The home base is a place where they can return and interact with other team members. There should be a spot in or near this teamwork area where the inspection team members can secure personal items such as coats, purses, laptops, and luggage. If practical, the home base should be near the location of the other meetings (see private meetings). Anyone can become disorientated in large, unfamiliar surroundings. A home base minimizes this effect. The SCO should provide the inspectors with phone numbers of department supervisors, medical directors, and the SCO to call if they become lost on campus or need to contact the team leader with a question. The SCO may consider using a beeper for this purpose.

Introductions should be the first item of the day. The introductory meeting is a chance for the hosting laboratory director to make welcoming remarks and for the inspector to introduce her/his team. Team members will pair up with the appropriate employees of their initial inspection assignments. The room for this initial meeting should be large enough to hold all of the principals and be in close proximity to the laboratory. Many times a general tour of the laboratory follows the introductory meeting. Arrange a formal general tour only for the individual(s) responsible for the Laboratory General Checklist. Those team members who want to see the whole facility may do so by informal arrangement later in the day (time permitting).

PRIVATE MEETINGS

The inspection team leader is expected to meet in private with the Hospital Administrator/Chief Executive Officer (or representative) and with the Chief of Staff/Chief Medical Officer (or representative). These are brief interviews of about 15 minutes each. The SCO should schedule these appointments for the team leader and provide a schedule for this ahead of time. The best time to hold these meetings is usually near the midpoint of the inspection, after the inspector has started to acquire an impression of the laboratory.

THE SUMMATION CONFERENCE

The Summation Conferences take place upon completion of the inspection. The team will meet 30-60 minutes beforehand in private for a team pre-summation meeting, to compare notes and prepare for the Summation Conference. This pre-summation conference might be held in the team's work area. The Summation Conference is usually held in a large classroom or auditorium. Many people will probably want to attend, and the team welcomes the participation of all interested parties. The Summation Conference typically will take 30-60 minutes but because the exact starting time may be unpredictable, the room should be reserved for as large a block of time as possible. Flexibility for extending this time is suggested.

Large inspections usually involve multiple laboratories. If for example, 10 laboratories are inspected by the team; covering the deficiencies in all of the labs at one big Summation Conference may be cumbersome. If the labs span more than one department or employer, a single large-group summation conference may not be appropriate. **Before the inspection, the SCO should ask each satellite laboratory director if she or he would prefer to have a separate Summation Conference.** Discuss these preferences with the inspector. One solution that can work well is to hold informal individual summation conferences "on the fly" (i.e., a private summation conference is held as the inspection of each small laboratory is completed). A group summation conference may still be organized to allow the

discussion of common themes and to allow laboratorians to ask the questions, clarify citations, and challenge deficiency findings.

MEALS FOR TEAM MEMBERS

There is neither requirement nor expectation that the laboratory provide food and beverages for the inspection team. Most laboratories do provide modest fare. Elegant presentations are inappropriate, and sit-down banquets waste valuable time. The luncheon plans the laboratory chooses to make for the team's comfort should be communicated to the team ahead of time.

Meals such as breakfast and dinner are outside of the hours of the inspection and should be handled by the team itself (the SCO might provide a list of suggested restaurants). The team would appreciate access to coffee or soft drinks at or near its home base in the laboratory. The most efficient lunches are cold buffet or box lunches. Team members will want to break away for lunch at a convenient point, which may vary with assignment. The luncheon room should be reserved for an extended period to allow individual team members to manage their time most effectively.

Team members working off-site at satellite locations should be offered similar hospitality or a list of nearby restaurants.

SUPPLIES AND SERVICES

The inspection team will need some supplies and services while on-site. In order to help the inspection proceed more smoothly, work out with the inspection team the mechanism for obtaining the following items before the inspection:

1. **Photocopies:** The ISR Part B must be copied for the laboratory before the team leaves. Sometimes team members may ask for copies of procedures, worksheets, or reports. The SCO should inform the laboratory supervisors concerning the local "ground rules" for photocopying. The hospitality of even the most generous laboratory can be strained by excessive requests. It is quite appropriate to ask the inspection team leader to keep photocopying requests modest.

2. **Telephone Calls:** The Laboratory Accreditation Program office can be called during regular business hours, Monday through Friday 8:00 AM to 5:00 PM Central Time, during the inspection, via the College's toll-free number 800-323-4040 (option 2 for LAP, then option 2 for checklist question interpretation) or 847-832-7000, extension 6065.

3. **Personal Protective Equipment (PPE)**

   The SCO should arrange for PPE. In most cases the only PPE needed will be laboratory coats and gloves, but arrangements should be made for additional items as needed. For example, an inspector visiting an autopsy suite during a postmortem examination should be provided with appropriate PPE.

SITE COORDINATOR'S CHECK-OFF LIST

Preliminary Tasks

☐ Determine which functions the laboratory director has designated to the site coordinator.

☐ Request copies of correspondence from the inspection team for all areas.

☐ Make sure documentation of correction of deficiencies is complete:
- From the last on-site inspection.
- From the self-evaluation.

☐ Call the CAP office for list of all laboratories to be included in the inspection.

☐ Contact the director of each special function laboratory on the campus.
- Offer to coordinate the inspection.
- List any special requests of the inspection team.

☐ Make a preliminary list of recommended dates for the inspection **(must be within the 30 calendar days before the laboratory's accreditation anniversary date).**

Telephone Call to Inspector

☐ Introduce yourself and describe your role as Site Coordinator.

☐ Determine who will coordinate the schedule and logistics for the inspection team. (Will the inspector team leader appoint a team coordinator?)

☐ Suggest hotel accommodations.

To Be Accomplished Six Weeks before the Inspection

☐ Check again with CAP to determine whether there have been any late additions to the list of included laboratories.

☐ Request a list of team members, their credentials, assignments, and special needs from the team leader if not already provided.

☐ Ensure that the team has appropriate transportation to and from its hotel.

☐ In concert with the team coordinator, schedule interviews with the:
- Hospital Administrator/Chief Executive Officer.
- Chief of Staff/Chief Medical Officer.

☐ Prepare the list of laboratory employees who will be working directly with the inspection team, and include their phone numbers and/or pager numbers.

☐ Reserve the meeting rooms.
- "Home base" or staging area for the team (all day).
- Introductory meeting (morning).
- Summation conference (afternoon).

☐ Discuss personal protective equipment (PPE) needs with team leader or coordinator.

☐ Provide the team with a list of recommended local restaurants.

To Have Ready for the Inspection

☐ Know where the team will be staying and how they will be getting to and from the airport.

☐ Establish a mechanism to escort the team members to the individual laboratories:
- For special function labs, determine how inspector will get to the laboratory and back.
- For satellite labs, provide for ground transportation.

☐ Provide a quiet room where centralized records will be available throughout the course of the inspection.

☐ Have PPE available as needed.

☐ Provide food and drink:
- Arrange for box lunches or simple buffet for a working lunch.
- Have cold drinks or coffee available in or near staging area for the afternoon.

☐ Provide for prompt photocopying of the ISR Part B following the summation conference.

Post-Inspection Tasks

☐ Remind laboratory staff that the documented responses, based on the ISR handwritten deficiencies, must be returned to the CAP office within 30 calendar days of the inspection.

☐ Coordinate the return of deficiency response materials to the CAP office.

Appendix G:
Retention of Laboratory Records and Materials

The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). The College of American Pathologists urges laboratories to retain records and/or materials for a longer period of time than specified when such would be appropriate for patient care, education, or quality management needs. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA '88 regulations; therefore any applicable state or federal laws should be reviewed carefully when individual laboratories develop their record retention policies.

MATERIAL / RECORD	**PERIOD OF RETENTION**
General Laboratory	
Accession log records	2 years
Maintenance/instrument maintenance	2 years
Quality control records	2 years
Surgical Pathology (including bone marrow)	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Cytology	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine needle aspiration slides	10 years
Reports	10 years
Non-Forensic Autopsy Records	
Wet tissue	3 months after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Forensic Autopsy Records	
**Wet stock tissue	1 year

Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log records	Indefinitely
Body fluids and tissues for toxicology	1 year
Dried bloodstain or frozen tissues for DNA	Indefinitely

MATERIAL / RECORD	PERIOD OF RETENTION
Clinical Pathology Records	
Patient test records	2 years
Serum/CSF/body fluids (except urine)	48 hours
Urine	24 hours
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides — microbiology (Gram, trichrome, etc.)	7 days
Cytogenetics Records	
Permanently stained slides	3 years
Fluorochrome stained slides	At the discretion of the laboratory director
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized, **prints or negatives)	20 years
Blood Bank	
Donor records	10 years
Patient Records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipients protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from blood donors units and recipients	7 days post-transfusion

***Revised 11/05*

Appendix H:
Glossary of Terms

Accreditation
The process of determining that a specific AU meets program-specific standards; for instance, the *Standards for Accreditation* as defined and published by the CAP.

Accreditation Cycle
The sequence of events spanning a two-year period that leads to an accreditation decision.

Accreditation Packet
Sent to each AU following a decision to grant accreditation. The packet contains a Certificate of Accreditation, CAP Letter of Accreditation, Final List of Deficiencies, and Press Release.

Accreditation Unit (AU)
The laboratory, department, or other organizational unit that is evaluated and can receive accreditation. While an AU is flexibly defined, it usually has a unique CLIA number, is located in one building or campus, and under the leadership of a single director who is named on the CLIA certificate.

Activity Menu, Master
The list of all tests and non-test activities that could be performed by an AU.

Activity Menu, AU-Specific
The list of tests and non-test activities specific to an AU. The AU-specific activity menu is used to create the customized checklists, monitor PT, inspect, and report accreditation.

Anniversary Date
The fixed date at which the laboratory accreditation will lapse unless the AU reapplies or is awaiting an accreditation decision. Each two-year accreditation cycle begins and ends with the Anniversary Date.

Application
A form(s) completed by the AU to initiate the CAP accreditation process.

Assigning Commissioner
The commissioner who appoints an inspection team leader.

AU
See Accreditation Unit.

AU-specific Activity Menu
See Activity Menu, AU-specific.

CAP-accepted Proficiency Testing
A proficiency testing (PT) program whose application has been evaluated and determined to meet the CAP Commission on Laboratory Accreditation criteria for alternative proficiency testing programs. CMS approval of a PT provider does not constitute CAP approval. A list of current CAP-accepted PT providers can be obtained by calling the College's customer service department at 800-323-4040, extension 6515.

CDC
Centers for Disease Control and Prevention.

Change of Discipline Form
A form sent to an AU after it has indicated a change in services that create an additional discipline. The AU indicates the activities in which it participates, so that they may be added to the AU-specific Activity Menu, as well as the volume of testing performed and supervision of the discipline. The Regional Commissioner will use this data to evaluate whether to order a non-routine inspection.

Checklist, Custom
A checklist that includes only those disciplines and subdisciplines that apply to the laboratory, as determined by the AU-specific activity menu. In a customized checklist, some method-specific and analyte-specific groups of questions, such as electrophoresis, factor assay, or sweat chloride, are eliminated when the AU does not perform these procedures.

Checklist
A detailed series of questions designed to evaluate whether the laboratory meets the *Standards for Laboratory Accreditation*. Each checklist is discipline-specific and serves as a tool to guide the conduct of the inspection. Each checklist item is classified by the CLA as Phase I or Phase II. Failure to meet the requirements of a Phase II item may have a serious effect on patient care or worker safety; Phase I items are less serious.

CLA
See Commission on Laboratory Accreditation.

CLIA (Clinical Laboratory Improvement Act) Number
An ID number assigned to a laboratory by CMS.

Clinical Laboratory
A facility engaged in the testing of specimens for the diagnosis and management of disease. A Clinical Laboratory usually has one CLIA number, is located in one building or campus under the leadership of a single director who is named on the CLIA certificate, and is owned by one entity.

CMS
Stands for Centers for Medicare and Medicaid Services [formerly the Health Care Financing Administration (HCFA)]. An agency within the U.S. Department of Health and Human Services (DHHS) that administers Medicaid, Medicare, and Child Health Insurance programs, and enforces the laws known as CLIA (Clinical Laboratory Improvement Amendments). The most recent of these was passed by the U.S. Congress in 1988 (CLIA ’88).

Commission on Laboratory Accreditation (CLA)
A group of CAP members appointed by the CAP president that implement accreditation policy. It consists of Regional Commissioners, Special Commissioners, and the Chair.

Commissioner, Deputy or Division or State
Individuals responsible for the assignment of inspection team leaders.

Commissioner, Regional
Individuals responsible for overseeing Laboratory Accreditation Program activities and recommending accreditation decisions.

Commissioner, Special
Individuals responsible for special activities within the Commission on Laboratory Accreditation. Titles of Special Commissioners include: Checklist Commissioner; Education Commissioner; Special Commissioner for State and Federal Legislative and Regulatory Issues; Special Commissioner for Non-Routine Processes; Special Commissioner for Systems; Toxicology Commissioner; and Reproductive Laboratory Accreditation Program Commissioner.

Custom Checklist
See Checklist, Custom.

Denial of Accreditation
The determination that a laboratory does not meet the CAP *Standards for Laboratory Accreditation*.

Director
An AU-appointed individual who meets the qualifications and fulfills the responsibilities identified in Standard I of the *Standards for Laboratory Accrditation*. The accreditation of a laboratory is tied to both the laboratory itself and the director.

Discipline
A CAP-defined term used to describe testing grouped within a major category of clinical laboratory science (e.g., Hematology, Microbiology, and Transfusion Medicine).

Comprehensive Online Team Leader Self-Study
A self-paced web-based education program designed to familiarize an individual with the Inspection responsibilities of the Team Leader.

Comprehensive Online Team Member Self-Study
A self-paced web-based education program designed to familiarize an individual with the Inspection responsibilities of the Team Member.

Final List of Deficiencies
A document included in the Accreditation Packet that lists deficiencies (if any) that were found during an AU's last on-site accreditation inspection. It does not include any deficiencies that were removed.

Forensic Drug Testing (FDT)
A CAP program that accredits laboratories performing drug testing for non-medical purposes (i.e., workplace drug testing).

FDT
See Forensic Drug Testing.

IE
See Inspection Event.

II
See Inspection Instance.

Immediate Review Criteria (IRC)
Findings that indicate that review of a laboratory's inspection results should be given a higher priority throughout the accreditation review process. Such findings include an excessive percentage of deficiencies or problems with proficiency testing.

Deficiency
Failing to meet the requirements of a specific checklist item. Deficiencies are currently classified as Phase I (i.e., minor deficiencies) and Phase II (i.e., severe deficiencies).

Deficiency Response
For each deficiency cited, the laboratory is required to submit an Inspection Deficiency Response within 30 calendar days after the inspection. For Phase I deficiencies, the AU must submit a statement describing measures taken to correct the deficiencies. For Phase II deficiencies, the AU needs to submit a statement of corrective action and supporting documentation showing that steps have been taken to correct the deficiency.

Inspection Event (IE)
An identifier used within the LAP to determine appropriate checklists for inspections. For every AU cycle, there is one Inspection Event for every Section Unit.

Inspection Instance (II)
A grouping of AUs and SUs for inspection purposes. These events are not necessarily related; however, they are grouped together for ease of inspection (usually a single campus or geographic area). This is subject to change for each AU cycle.

Inspection Unit (IU)
One or more accreditation units for the purpose of inspection. For purposes of assigning inspectors, an IU consists of one or more AUs that are to be inspected at the same time by one or more teams. This grouping is more static than an II. An IU is used to ensure that AUs of similar characteristics inspect each other. An IU is also used to track that an AU has fulfilled its inspection obligation.

Inspector
An experienced pathologist, resident, or fellow in pathology, clinical scientist, medical technologist, or other laboratory personnel, as appropriate.

Inspector's Inspection Packet
Contains all of the information and forms necessary to perform an on-site inspection.

Inspector's Summation Report (ISR)
A set of forms returned by the team leader containing the specific deficiencies cited during an inspection and the inspector's comments.

IRC Laboratory
See Immediate Review Criteria.

Laboratory Inspection Packet
A packet of information sent to the laboratory prior to the on-site inspection that contains the AU-specific Activity Menu, response sheets, and instructions on how and when to respond to deficiencies**.**

List of Deficiencies
An LAP computer system-generated listing of the checklist questions that were established as deficiencies at an inspection of a specific AU.

Master Activity Menu
See Activity Menu, Master.

Non-routine Inspection
Any on-site inspection performed in addition to the biennial routine on-site inspection. Non-routine inspections can be done for a variety of reasons, including a change of director, addition of disciplines, or investigation of a complaint.

Proficiency Testing (PT)
The process by which laboratories analyze simulated patient specimens; it includes the statistical evaluation of the results in order to assess individual laboratory performance as compared to laboratories using similar methods and reagents, or with expected results. See CAP-accepted PT.

Reapplication
A set of forms that a laboratory completes in order to provide updated information for the routine on-site inspection. A timely reapplication is required to continue participation in the accreditation program.

Reproductive Laboratory Accreditation Program (RLAP)
The CAP program with the focus of accrediting laboratories that perform Andrology and Embryology laboratory services.

Reviewing Commissioner
The commissioner who reviews the inspection information, including the Inspector's Summation Report and the laboratory's deficiency responses in order to decide if accreditation should be given.

RLAP
See Reproductive Laboratory Accreditation Program.

Scientific Director
A lab-appointed director associated with an AU (FUDT only).

Section Unit (SU)
An operational area, department, or other type of organizational unit within an AU (e.g., hematology, cytopathology, immunology). One or more comprise an AU. A supervisor is responsible for an SU.

Staff Inspector/Inspection Specialist
A CAP employee who conducts inspections.

Standards
The basis for the accreditation decision. The *Standards for Laboratory Accreditation* address broad requirements of four major laboratory issues: Qualification, Responsibilities, and Role of the Laboratory

Director; Physical Facilities and Safety; Quality Control and Performance Improvement; and Inspection Requirements. The laboratory must meet all four requirements in order to be accredited by CAP.

SU
See Section Unit.

Subdiscipline
A CAP-defined term used to describe related testing activities that reside under a particular discipline.

Supervisor
A person responsible for the daily activities of a Section Unit.

Surveys
Proficiency testing program offered by the College of American Pathologists.

Target Inspection Date
The date that signifies the end of the calendar day window during which the inspection should occur.

Termination
The process by which a laboratory's accreditation is ended. The reasons for termination include:

1. Denial of an AU's accreditation after an inspection.

Initiation of termination by the AU itself when it no longer wishes to participate in the Laboratory Accreditation Program. The AU is responsible for notifying the LAP staff of its intention to discontinue coverage under the LAP.

2. Failure to return reapplication materials within a specified time frame. The termination will occur after reminder options (Additional Documentation) have been exhausted. Letters will be sent to the AU and the Regional Commissioner stating that the laboratory has been terminated because reapplication materials were not received.
3. Merger of two or more AUs, which results in the accreditation of a single AU. The AUs that are no longer effective will be terminated and the surviving AU's record will be updated to reflect all changes due to the merger.
4. Failure to meet the *Standards for Laboratory Accreditation*.

Test
An analysis of a human specimen, which typically yields a clinical result.

Variant Proficiency Test Performance
An analyte result that falls outside the limits of acceptability or differs from the acceptable response.

Variant Proficiency Testing Performance by Laboratory Report
A report, included in the inspector's packet, that shows all variant PT performances for the last six PT mailing events. This report is intended to help the inspector focus on possible problem areas.

Volunteer Inspector
A person who conducts inspections for the CAP Laboratory Accreditation Program without monetary compensation. Inspections are typically on behalf of the Inspection Unit with which the inspector is affiliated.

Appendix I:
Accreditation Requirements when a PT Result Is Linked to a Nongraded Exception Code

PT providers use exception codes that signify the proficiency testing (PT) for an analyte has not been graded. For CAP Surveys, the ungraded exception code is located on the evaluation report in brackets to the right of the result. The laboratory must identify all of the analytes with an ungraded exception code and investigate the acceptability of its performance with the same rigor as if it were an unacceptable performance.

Whenever an ungraded exception code is present, review the all-participant statistics for any explanatory information. The appropriate investigative procedures for the following codes include but are not limited to:

Codes	***Exception Reason Code Description***	***Action Required***
11	Unable to analyze	Document why the specimens were not analyzed (e.g., instrument not functioning or reagents not available). Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	No appropriate target/response; cannot be graded	Document that the laboratory compared its results to the modal (most common) result. Perform and document the corrective action if required.
21	Specimen Problem	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider. Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
22	Result is outside the method/ instrument reportable range	Document the comparison of results to the proper peer group statistics and peer group information supplied by the PT Provider. Perform and document the corrective action if required.
24	Incorrect response due to failure to provide a valid response code	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial	Document the investigation of the result as if they were unacceptable and review the proper peer group statistics to gain knowledge of the reason your response is not appropriate.
26	Educational Challenge	Response to the CAP is not required. Laboratory should document its review.
27	Lack of participant or referee consensus	Document that the laboratory compared its results to the modal (most common) result. Perform and document corrective action if required
28	Response qualified with a greater than or less than sign; unable to quantitate	Document the laboratory's self-evaluation against the proper peer group statistics supplied by the PT Provider. Perform and document corrective action, if appropriate.

30	Scientific Committee Decision	Document that the laboratory has reviewed the proper peer group statistics supplied by the PT Provider.
33	Specimen determined to be unsatisfactory after contacting the CAP	Document that the laboratory has contacted the CAP and no replacement specimens were available. Perform and document alternative PT for the period that commercial PT was not tested to the same level and extent that would have been tested.
40	Results for this kit were not received	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper peer group statistics supplied by the PT Provider.
41	Results for this kit were received past the evaluation cut-off date	
42	No credit assigned due to absence of response	The Participant Summary booklet mailed with the proficiency testing evaluation indicates which tests are graded (see evaluation criteria) and which tests are Not Evaluated/Educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. The code 42 that appears on the evaluation is not a penalty. If a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for all challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the Kit Instructions and/or the Result Form. Document corrective actions to prevent future failures.
44	This drug is not included in our test menu; use of this code counts as a correct response	Verification that the drug is not tested on patient samples and document to ensure proper future reporting.
77	Improper use of the exception code for this mailing	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
* 35, 43, 88, 92	Various codes	No action required by the LAP.

12-06

Appendix J:
Team Leader Inspection Planner

Complete each item listed below

1) Arrange the inspection

- ❑ Do not contact the laboratory if this is an unannounced inspection. If this is an announced inspection, contact the Laboratory Director to set an inspection date.
- ❑ Begin to select your team, including the number and types of inspectors needed. For instance, one inspector for Laboratory General and one for the following checklist combinations: Hematology and Urinalysis; Microbiology and Immunology; and Anatomic Pathology and Cytopathology. Transfusion Medicine can be combined with another checklist (such as Immunology or Point of Care) if the laboratory does not have a donor center.
- ❑ If the laboratory is performing Cytogenetics, Flow Cytometry, Histocompatibility, or Molecular Pathology, a list of qualified inspectors within your geographic region is provided in the inspection packet and **must** be used. Please contact potential inspectors directly to determine availability. Contact Jennifer Williams, Inspector Database Specialist (800-323-4040, ext. 7380), if you need the names of additional qualified inspectors. The selected inspector should have specialty expertise and be actively involved in the discipline.
- ❑ If there is a Cytopathology inspection, the inspector must be a pathologist or cytotechnologist who is actively involved with Cytopathology. Several hours should be allotted for the inspection so that there is enough time for a detailed slide review, direct observation of technical procedures, and a careful review of quality improvement monitors.
- ❑ Identify all team members and gain commitments from them.

2) When the inspection packet arrives, review the contents immediately.

- ❑ Verify the number and location of laboratories to be inspected.
- ❑ Verify the checklists to be used for the inspection.
- ❑ Review Activity Menus and instrumentation lists; determine skill sets necessary for team members.
- ❑ Confirm commitment of all team members. If this is an announced inspection, send a confirmation letter to the Laboratory Director (sample letter downloadable in Word format from the "Your Inspection Resource" CD-Rom in the inspection packet) that indicates the date and time of the inspection and the composition of the inspection team.
- ❑ If you have not already done so, contact the CAP and schedule an inspection date.
- ❑ Call CAP Travel Office (800-323-4040, ext. 7800) to make travel and/or hotel arrangements for the team, if necessary, and complete the travel request form. **If air travel is required, arrangements must be made through the CAP Travel Desk. Hotel reservations must be made through the CAP Travel Desk if more than 10 total hotel nights are being booked for the team.** To ensure the best availability of airfare

and hotel choices, whenever possible, please contact the Travel Desk at least one month prior to travel.

3) Create a packet for each team member inspector with the following items:

- ❑ Cover memo setting out the timing and conduct of the inspection (find sample on "Your Inspection Resource" CD-ROM in the inspection packet).
- ❑ Copy of the Team Member Inspection Planner
- ❑ Activity Menus and instrumentation lists for each inspector's checklist(s)
- ❑ Copy of the Variant PT by Laboratory Report, when applicable
- ❑ Copies of the deficiencies found at the prior inspection
- ❑ Copies of checklist-specific sections from the Laboratory Accreditation Manual
- ❑ Checklist(s) and related Deficiency and Recommendations pages from the Inspector's Summation Report (ISR)
- ❑ Plane tickets, hotel reservation information, etc., as needed

4) Prepare the team

- ❑ Meet with the inspection team at least two weeks prior to the inspection to hand out the packets and discuss travel arrangements, inspection conduct, timing, etc.
- ❑ Ensure you and your team members have completed Inspector Training. Visit the CAP Web site (http://www.cap.org), click on "Accreditation and Laboratory Improvement"; then "Preparing to Inspect" to review training options. Inspector Training is available at no cost. Direct any education question to 800-323-4040, ext. 7525.

5) During the inspection

- ❑ Arrive on time. Inspections of full-service laboratories typically begin before 9 AM and conclude between 4 PM and 6 PM. Be sure to allow adequate time for a thorough inspection.
- ❑ Some labs may require a photo ID to gain entrance on the day of the inspection. Be sure you and your team members have adequate identification (driver's license, state ID, passport).
- ❑ Introduce the team to the laboratory personnel with whom each will be working.
- ❑ Discuss arrangements for lunch, summation conference, interviews for the team leader, working area for the team, etc.
- ❑ Remind team to discuss all deficiencies with the supervisor/laboratory representative as they are identified and summarize them at the end of the section inspection.
- ❑ Instruct team members to review deficiencies cited at the last on-site inspection, paying particular attention to the recurring deficiencies. Ensure that the laboratory is employing the procedures to processes that are appropriate to meet the College's *Standards*.
- ❑ Maintain contact with the team during the day (e.g., brief mid-morning meeting, working lunch, etc.) to verify progress, answer questions, and redirect resources if necessary.
- ❑ Call the CAP during the day of the inspection (800-323-4040, ext. 6065) if there are questions that the team cannot answer.

6) Pre-summation

- Meet with the team prior to the summation conference to discuss all deficiencies, answer team members' questions, and establish consistency.
- Remind team to complete the Deficiency and Recommendations forms as follows:
  - Complete forms prior to summation conference.
  - For each citation, enter the checklist number and the specific reason the laboratory is deficient.
  - Complete Cytopathology slide review grid on the ISR.
  - Print name and credentials; sign and date each ISR page.
  - Have inspectors fill out the Inspection Team Member Form and CME/CE forms.

7) Summation conference

- Discuss all deficiencies and recommendations.
- Obtain the Laboratory Director's signature on page 3 of Part A of the ISR.
- Leave a copy of the Deficiencies and Recommendations with the laboratory.
- Remind laboratory personnel that they have 30 days to respond to all deficiencies. Explain how to respond to both Phase I and Phase II deficiencies.

8) After the inspection

- Complete page 1 of Part A of the ISR, and note comments on page 2.
- Return the complete Inspector's Summation Report and the list of inspectors to the CAP within 24 hours using the pre-paid DHL mailer in the packet.
- Collect Team Leader/Member Evaluation forms and expense receipts, fill out reimbursement form, and mail to CAP. Please write legibly, provide the address for the reimbursement check, and sign the reimbursement form. Accounts Payable cannot issue checks without the signature of the inspector to be reimbursed.
- Discard checklists and any other information regarding the inspection.

Appendix K:
Team Member Inspection Planner

Complete each item listed below

Do not contact the Laboratory Director or any member of the laboratory staff regarding this inspection.

1. **Obtain a copy of the Laboratory Accreditation Manual from the Team Leader or online at http://www.cap.org. Review the following pertinent sections:**
   - ❑ Definitions of Phase I and Phase II deficiencies.
   - ❑ Commission philosophies.
   - ❑ Conducting the inspection; General Principles.
   - ❑ Inspecting the Laboratory Sections (general guidelines for each checklist); review yours and Requirements Common to All Laboratory Sections.
   - ❑ The Summation Conference.

2. **Review your inspection materials prior to the inspection date. Each checklist should have related:**
   - ❑ Deficiency (pink) and Recommendations (yellow) forms.
   - ❑ AU Activity Menu (list of procedures and analytes).
   - ❑ Instrumentation list.
   - ❑ Variant PT by Laboratory Report (if failures have occurred).
   - ❑ Inspector Summation Report from previous inspection.

3. **Examine inspection materials carefully prior to the inspection date to ensure that you are familiar with the checklist version used and the procedures/analytes to be inspected. Other ways to prepare are:**
   - ❑ Access Team Member Inspector Training at the CAP Web site (http://www.cap.org).
   - ❑ If you have questions about interpretation of checklist items, e-mail a question to the CAP (accred@cap.org), or phone 847-832-7000 or 800-323-4040, extension 6065.
   - ❑ Be sure that you feel qualified to carry out the inspection(s) assigned. Discuss any questions with the inspection team leader prior to the inspection.
   - ❑ Perform a mock inspection of your own laboratory using the checklist provided.

4. **Inspection packet should also contain:**
   - ❑ Name tag (wear at all times during the inspection).
   - ❑ Team Member Evaluation form (complete after inspection and return with packet to CAP).
   - ❑ Inspection Team Member form and CME/CE form (must be completed after inspection and returned with packet to CAP).
   - ❑ Reimbursement form (if travel is involved). Please write legibly, provide the address for the reimbursement check, and sign the reimbursement form. Accounts payable cannot issue checks without the signature of the inspector to be reimbursed.

5. **During the inspection:**
    - Arrive on time.
    - Maintain a professional attitude at all times!
    - If inspecting more than one section, develop a schedule with the section supervisors.
    - For each section, review documentation and observe actual testing.
    - Review deficiencies cited at the last on-site inspection, paying particular attention to recurring deficiencies. Ensure that the laboratory is following the procedures or processes that are appropriate to meet the College's *Standards*.
    - Discuss all deficiencies with the supervisor/laboratory representative as they are identified and summarize them at the end of the section inspection.
    - During lunchtime, inform the team leader of your progress.
    - If uncertain about the interpretation of a checklist question, discuss with the team leader. If still uncertain, call the CAP at 1-800-323-4040, ext. 6065.
6. **At the pre-summation conference:**
    - Discuss all deficiencies with the team leader. Warn the team leader if there has been a disagreement over a checklist item with the supervisor.
    - Write deficiencies on the appropriate deficiency (pink) page for each checklist. For each citation, record the checklist number and the specific reason the laboratory is deficient. If no deficiencies, check the "This lab section had no deficiencies" box at the top of the page.
    - Write recommendations on the appropriate Recommendations (yellow) page for each checklist. Recommendations need not relate to a specific checklist question.
    - Print and sign your name in the bottom section of each page for Deficiencies and Recommendations.

7. **When presenting your findings at the summation conference:**
    - Thank the supervisor that you worked with by name.
    - "Findings" include both positive and negative observations. Compliments for good work set a favorable tone.
    - Present deficiencies in a straightforward manner. Do not mix recommendations with deficiencies.
    - If the lab personnel disagree with a citation, listen carefully to their explanation, but do not get into an argument. If you continue to believe your finding is a deficiency, the lab can provide documentation to the CAP why it believes it is in compliance. The CAP will decide which interpretation is correct.
    - Return Deficiencies and Recommendations forms to the team leader for collation and copying. Return even if not used.
    - Don't be in a rush to leave immediately after summation. If you have performed your job with fairness and respect, there are usually good feelings to be shared at the end of the day.

8. **Navigating the CAP Web site**
    - Finding the Laboratory Accreditation Program pages:
        - Enter the following address in your browser: http://www.cap.org. This brings up the CAP home page.
        - Click on "Accreditation and Laboratory Improvement."

- Finding the Laboratory Accreditation Program Manual:
  - On the Laboratory Accreditation page, click on the heading “Resources for Labs.”
  - On this page, you will find both the “Standards for Laboratory Accreditation” and the “Laboratory Accreditation Manual.”
- Finding online inspector training materials:
  - On the Laboratory Accreditation page, click on “Preparing to Inspect” (this will give you access to the:

1. Comprehensive Online Team Member Self-Study,
2. Comprehensive Online Team Leader Self-Study,
3. Accreditation Virtual Audioconference Library,
4. Other training activities and resources.

Appendix L:
College of American Pathologists Laboratory Accreditation Program Policies
(October 2006)

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1. ACCREDITATION

1.01 Requirements for Accreditation

1.01.a.1. To be considered for accreditation by the Laboratory Accreditation Program, a laboratory must submit an appropriately completed application and necessary deposits or fees.

1.01.a.2. To be accredited by the Laboratory Accreditation Program, a laboratory must be judged by the Commission on Laboratory Accreditation to be in compliance with the *Standards for Laboratory Accreditation*, the *Standards for the Accreditation of Reproductive Laboratories*, or the *Standards for the Accreditation of Forensic Drug Testing*, whichever is applicable.

1.01.b. For each two-year accreditation period, a laboratory must provide an inspection team of a size and composition similar to that required for its own inspection, if requested to do so by the Assigning Commissioner.

1.01.c.1. Laboratories located outside the United States, Mexico, and Canada will be required to pay round trip business class airfare(s) for inspector(s), at the discretion of the Chair of the Commission, in addition to any ordinary accreditation fees, if it is necessary to assign an inspector from another country.

1.01.c.2. Laboratories located within the United States, Mexico, and Canada will not be required to pay travel expenses for inspector(s).

1.01.d.1. A laboratory must submit to a complete inspection. The Commission will not inspect or accredit a portion of a single cohesive laboratory except under special and/or unusual circumstances and then only by approval of the Reviewing Commissioner.

1.01.d.2. If a laboratory fails to identify any test or testing site under its CLIA number, the Commission may elect to conduct a non-routine inspection of the test or testing site at the laboratory's expense.

1.02 Accreditation Fees

1.02.a. Fees for participation in the Laboratory Accreditation Programs shall apply annually.

1.02.b. Additional fees shall be assessed for inspections that follow accreditation denial.

1.02.c. Additional fees may be assessed for certain non-routine inspections.

1.02.d. Accreditation fees are non-refundable.

1.02.e. Alternative fee schedules may be defined by contractual arrangement.

1.03 Participation in Proficiency Testing

1.03.a.1. CAP-accredited laboratories must participate in a proficiency testing program for each analyte for which they provide testing. Subscription to a Commission-approved PT program is

required where available. The laboratory must engage in an appropriate alternative when no formal program is available. The Commission or Reviewing Commissioners may grant exceptions to this policy.

1.03.a.2. CAP-accredited laboratories must develop an acceptable plan to validate performance, at least semi-annually, for analytes for which graded proficiency testing is not available. Such a plan might include two technologists testing the same specimen, sharing a specimen with another laboratory, or using ungraded proficiency testing materials.

1.03.b. When an accredited laboratory fails to demonstrate proficiency, as defined by the Commission, the laboratory must, on a timely basis and if requested, submit, for review by the Commission, appropriate documentation of its investigation of the cause of the unacceptable performance and of corrective actions taken, if any.

1.03.c. When an accredited laboratory demonstrates recurrent unacceptable (unsuccessful, insufficient, critical) performance in proficiency testing for an analyte, a sub-discipline or a discipline, the Commission may, as it deems necessary, impose sanctions to assure that the laboratory corrects the underlying problems and performs the tests in a manner that will not jeopardize patient safety.

1.04 Accreditation Checklists

1.04.a.1. The Checklist Committee of the Commission on Laboratory Accreditation is responsible for the development and maintenance of the Checklists.

1.04.a.2. The Checklist Committee obtains technical consultation for the Checklists from the various Resource Committees.

1.04.b. Checklists are used by the Commission and inspectors to evaluate a laboratory's compliance with the appropriate *Standards for Laboratory Accreditation*.

1.04.c. Except to the extent permitted by the fair use provisions of the Copyright Act, any entity that wishes to reprint or translate all or any part of any Checklist or to incorporate all or any part of any Checklist into any other work must first enter into a Checklist License Agreement by which the entity (a) acknowledges and agrees to respect the College's copyright in the Checklist, (b) agrees to make no deceptive claims with respect to its use of the Checklists or its relationship with the College, and (c) accepts such other conditions, including the payment of a royalty, as may be required by the Commission.

1.05 Release of Accreditation Information

1.05.a.1. Except as noted in sections 1.05.a.2, 1.05.d, and 1.17.c, the only information about an inspected laboratory that can be released is its current accreditation status, the date of its last on-site inspection, its accreditation status on any given date, and the date of its first accreditation continuous with the current accreditation.

Other than as specified in this section and in sections 1.05.a.2, 1.05.d, and 1.17.c, any information or material received by the College in connection with an inspected laboratory's participation in the Laboratory Accreditation Program is considered confidential and will not be released unless release is authorized by the laboratory director or is required by law.

Response to inquiries on CAP programs will be based on printed information, written committee policies and procedures, published data summaries, and program specifications.

1.05.a.2. If the Commission at any time learns of any laboratory practices that appear to be unlawful or unethical or that might pose significant risk to patients or laboratory personnel, the Commission may report such information, as it deems appropriate–even without authorization from the laboratory director.

1.05.a.3. The Laboratory Accreditation Program (LAP) will publish current accreditation status on the CAP Web site for public access. The LAP will not publish inspection reports, but instead will encourage the public to request such reports from the laboratory. Laboratories will be encouraged to develop their own disclosure policies.

1.05.b. Except as provided for in 1.05a.2, 1.05.d, and 1.17.c, the Laboratory Accreditation Program (LAP) shall not release specific information about a laboratory to agencies or organizations outside the College of American Pathologists without the written authorization of the laboratory director or other appropriately authorized individual.

1.05.c. All policies, procedures, and other internal documents relating to aggregate laboratory performance within the LAP shall not be released to agencies or organizations outside the CAP without authorization from the Chair of the Commission on Laboratory Accreditation (or designee).

1.05.d.1. If a laboratory is using CAP accreditation to meet the licensing requirements as required by regulations deriving from CLIA '88, the Laboratory Accreditation Program will release any documents to CMS as required by federal regulation or law.

1.05.d.2. If a laboratory is using CAP accreditation for purposes of JCAHO accreditation in an institution accredited by them, the Laboratory Accreditation Program will release any documents as required by contractual agreements between the two organizations.

1.05.d.3. If a laboratory is using CAP accreditation to meet licensing requirements of any State that has granted sub-deeming authority to the CAP, the Laboratory Accreditation Program will release any documents to that State as required under terms of the agreement or regulations granting sub-deeming authority.

1.05.e. The Laboratory Accreditation Program will release specific inspection and accreditation information regarding all accredited laboratories within a System to the System physician contact of that System.

1.05.f. The Laboratory Accreditation Program may release specific inspection and accreditation information regarding all accredited laboratories within an institution to the chief executive officer of that institution.

1.06 News Media Inquiries

1.06 All news media inquiries regarding the CAP Laboratory Accreditation Programs or accredited laboratories must be forwarded to the Vice-President, Division of Laboratory Accreditation Programs, as soon as possible.

1.07 Correction of Deficiencies

1.07.a.1. The Laboratory Director must address all Phase I deficiencies-whether correctable or not-in a written response to the Reviewing Commissioner, within the 30-day period following the routine on-site inspection. For non-routine inspections, the Commission may specify a shorter time period for the laboratory to submit responses.

1.07.a.2. The Reviewing Commissioner may recommend accreditation, denial, probation, suspension, or conditions of accreditation to the Accreditation Committee of the Council on Accreditation, based on an assessment of the impact of recurrent or large numbers of Phase I deficiencies upon laboratory performance and quality.

1.07.b.1. The Laboratory Director must correct all Phase II deficiencies in a written response to the Reviewing Commissioner, within the 30-day period following the routine on-site inspection. For non-routine inspections, the Commission may specify a shorter time period for the laboratory to submit responses.

1.07.b.2. The Laboratory Director must provide satisfactory documentation that plans of corrective action for all Phase II deficiencies have been implemented before accreditation can be extended to the laboratory.

1.07.b.3. Documented evidence of plans to correct serious space Phase II limitations (such as relocation or construction) must be submitted in writing to the Reviewing Commissioner. Progress on plans to correct serious space limitations (such as relocation or construction) must be observed from one inspection to the next.

1.07.c. The Reviewing Commissioner may reclassify an inspection recommendation when it appears that the issue noted should have been cited as a deficiency or request information and/or documentation regarding the issue.

1.07.d. The Reviewing Commissioner may grant a reasonable extension of the period allowed for correction of deficiencies.

1.08 Revocation/Denial of Accreditation

1.08.a.1. The Accreditation Committee of the Council on Accreditation may deny or revoke accreditation of a laboratory when it fails to meet the *Standards for Laboratory Accreditation* of the CAP Laboratory Accreditation Program or when the laboratory fails to comply with the policies and procedures of the Laboratory Accreditation Program.

1.08.a.2. A laboratory whose accreditation is denied or revoked shall be notified by express delivery, with signature required.

1.08.a.3. All accreditation denials and revocations will be reported within the appropriate specified time frame to appropriate oversight agencies.

1.08.b.1. A laboratory whose accreditation has been denied or revoked by the Accreditation Committee may seek reconsideration by that Committee based on additional information that it presents to the Committee within 30 days after notification of the accreditation decision.

1.08.b.2. A laboratory whose accreditation has been denied or revoked by the Accreditation Committee may appeal the decision to the Council on Accreditation within 30 days after notification of the decision. Such a laboratory may appeal after the initial decision of the Accreditation Committee or it may appeal after denial of a request for reconsideration by that Committee.

1.08.b.3 The Council shall consider a properly filed appeal within 30 days following receipt of the appeal.

1.08.b.4. The Council shall review each appeal and make a determination whether to invite representatives of the laboratory, at their expense, to appear before the Council to present and clarify relevant facts and to answer questions posed by the Council members. This determination shall be conveyed to the laboratory within 10 days following review of the appeal.

1.08.b.5. The Council shall act on any appeal at the meeting at which the appeal is heard unless the Council determines that it requires additional information. If the Council requests additional information, it shall decide the appeal at its next regularly scheduled meeting.

1.08.b.6. The decision of the Council on an appeal shall be conveyed to the laboratory promptly after the decision is made.

1.08.b.7. Neither request for reconsideration by the Accreditation Committee nor appeal to the Council on Accreditation shall stay the denial or revocation of accreditation.

1.08.b.8. If the denial or revocation of accreditation is overturned on reconsideration or appeal, the laboratory will be reinstated as of the time of the reversal, and the appropriate oversight agencies will be notified of the decision.

1.08.c.1. A laboratory denied or revoked accreditation may not reapply for accreditation until six months from the date of the notification of denial or revocation has elapsed.

1.08.c.2. A laboratory that has been denied or revoked accreditation and that has chosen to reapply for accreditation will be assessed fees equal to those fees assessed for a new application.

1.09 Accreditation with Conditions

1.09. The Laboratory Accreditation Program may grant accreditation with specific conditions, as determined by the Reviewing Commissioner, by the Executive Committee, or by the Commission.

1.10 Terms of Accreditation

1.10 The accreditation of a laboratory is valid for two years, unless otherwise specified as provided for in 1.09.

1.11 Lapse of Accreditation

1.11.a. A laboratory's accreditation will lapse, unless it submits a complete application for re-inspection on a timely basis that will allow the scheduling of an inspection within the six months prior to its next anniversary date.

1.11.a.1. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation in lieu of CMS licensure, the laboratory's accreditation will lapse on its anniversary date and CMS will be notified.

1.11.a.2. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation to satisfy JCAHO accreditation requirements, the laboratory's accreditation will lapse on its anniversary date and JCAHO will be notified.

1.11.a.3. If a laboratory fails to submit a reapplication on a timely basis and is using CAP accreditation in lieu of State licensure, the laboratory's accreditation will lapse on its anniversary date and the State will be notified.

1.11.b. Refusal to provide an inspection team of a size and composition similar to that required for its own inspection, a team leader, or appropriate team members if unable to provide a team leader, may result in non-renewal of the laboratory's accreditation on its anniversary date, at the discretion of the Executive Committee of the Commission.

1.11.c. The LAP will not accept or process a reapplication, schedule an on-site inspection, or accredit any laboratory that has not paid in full its annual accreditation fee or other accreditation-associated charges (e.g., charges for international travel or non-routine inspections). Failure to pay for proficiency testing materials is not considered to be failure to pay accreditation-associated charges.

1.12 Change of Director

1.12.a. Accreditation by the College does not automatically continue upon any change of Director, permanent, or interim or acting.

1.12.b. A laboratory must notify the Laboratory Accreditation Program in writing within 30 days when it undergoes a change of director, and include a copy of the new director's curriculum vitae, an organizational chart indicating the director's position in the laboratory and within the

institution, completed documentation of the laboratory director's qualifications and responsibilities, and additional information as requested by the College.

1.12.c.1. Upon a change of director, the laboratory may be required to undergo, and to pay for, a non-routine on-site inspection.

1.12.c.2. A Reviewing Commissioner may waive the requirement for a non-routine inspection after change of director, if no substantive changes in the operation of the laboratory have been made and all the requirements of the governing *Standards for Laboratory Accreditation* continue to be met.

1.12.c.3. If the requirement for non-routine inspection after change of director is waived, the laboratory will retain its accreditation until its next regularly scheduled on-site inspection.

1.13 Change of Ownership or Location

1.13.a. Accreditation by the College does not automatically continue upon change of ownership or location.

1.13.b. A laboratory must notify the Laboratory Accreditation Program within 30 days of any change in ownership or location and provide appropriate demographic information. A change in location is defined as an actual physical change in location, whether or not there has been a change in address. Such notification also satisfies CLIA '88 regulatory requirements.

1.13.c.1. Upon a change of ownership or location, the laboratory may be required to undergo and pay for a non-routine on-site inspection.

1.13.c.2. A Reviewing Commissioner may waive the requirement for a non-routine inspection after change of ownership or location, if no substantive changes in the operation of the laboratory have been made and all the requirements of the governing *Standards for Laboratory Accreditation* continue to be met.

1.13.c.3. If the requirement for non-routine inspection after change of ownership or location is waived, the laboratory will retain its accreditation until its next regularly scheduled on-site inspection.

1.14 Revision of *Standards*

1.14.a. The Commission on Laboratory Accreditation is responsible for implementing the *Standards for Laboratory Accreditation*.

1.14.b. Any proposed change in the *Standards for Laboratory Accreditation* must be submitted to the Commission on Laboratory Accreditation for review. .

1.14.c. Changes to the *Standards for Laboratory Accreditation* recommended by the Commission on Laboratory Accreditation must be submitted to the Council on Accreditation for review and approval.

1.14.d. Changes to the *Standards for Laboratory Accreditation* approved by the Council on Accreditation must be submitted to the Board of Governors for review and approval for implementation.

1.15 Extension of Accreditation

1.15.a. If a laboratory is performing testing on patient specimens, it must be prepared to undergo an on-site inspection at any time.

1.15.b. The Commission cannot extend the term of accreditation for a laboratory beyond two years. If the Reviewing Commissioner is unable to make an accreditation decision on a timely basis, the laboratory remains accredited until that decision has been made.

1.16 Misrepresentation of Accreditation

1.16. Deliberate misrepresentation of accreditation or accreditation status by a laboratory may result in sanctions that may take the form of legal action, refusal to process applications or reapplications, or revocation of accreditation.

1.17 Investigation of Complaints

1.17.a.1. Every complaint involving a CAP-accredited laboratory must be investigated. The results of such investigations that indicate a failure of an accredited laboratory to meet the *Standards* shall be referred to the Accreditation Committee for review.

1.17.a.2. As part of the investigation of a complaint the Commission may require the laboratory to undergo and to pay for an inspection (which may be announced or unannounced) to determine whether the laboratory is in compliance with the *Standards*.

1.17.b. All reasonable efforts shall be made to maintain the confidentiality of investigational files.

1.17.b.1. Files shall be secured to a reasonable and practical degree.

1.17.b.2. The complainant's identity shall not be disclosed without permission (written or oral) when the complaint was lodged in confidence.

1.17.c. The Laboratory Accreditation Program will, as appropriate, respond to a complainant after a complaint investigation has been completed, with the results of that investigation. The level of detail provided will be consistent with the need to protect the confidentiality of the information provided by the laboratory and the need to have information communicated to the complainant. The Complaints Committee will review specific information released to the complainant prior to its release.

1.18 Withdrawal from the Laboratory Accreditation Program

1.18.a. A laboratory may withdraw from the Laboratory Accreditation Program at any time.

1.18.b. To withdraw, a laboratory must submit a written request for withdrawal.

1.18.c. Accreditation will cease on either the date of notification or a future date specified by the laboratory. The date specified may not be later than the laboratory's anniversary date.

1.18.d.1. If the withdrawing laboratory is using CAP accreditation in lieu of CMS licensure and withdraws prior to its initial inspection or a subsequent re-inspection or mid-cycle, CMS will be notified ONLY of the withdrawal.

1.18.d.2. If the withdrawing laboratory is using CAP accreditation in lieu of CMS licensure and withdraws after its initial inspection or subsequent re-inspection and before the associated accreditation decision, CMS will be notified of the withdrawal and will be provided with the list of deficiencies.

1.18.e.1. If the withdrawing laboratory is using CAP accreditation to satisfy JCAHO accreditation requirements and withdraws prior to its initial inspection or a subsequent re-inspection or mid-cycle, JCAHO will be notified ONLY of the withdrawal.

1.18.e.2. If the withdrawing laboratory is using CAP accreditation to satisfy JCAHO accreditation requirements and withdraws after its initial inspection or subsequent re-inspection and before the associated accreditation decision, JCAHO will be notified of the withdrawal.

1.18.f.1. If the withdrawing laboratory is using CAP accreditation in lieu of State licensure in an exempt State and withdraws prior to its initial inspection or a subsequent re-inspection or mid-cycle, the State will be notified ONLY of the withdrawal.

1.18.f.2. If the withdrawing laboratory is using CAP accreditation in lieu of State licensure in an exempt State and withdraws after its initial inspection or subsequent re-inspection and before the associated accreditation decision, the State will be notified of the withdrawal and will be provided with the list of deficiencies.

1.19 Conflict of Accreditation Requirements with Prevailing Law or Regulation

1.19. A laboratory shall not be required to comply with an individual Checklist requirement if it contravenes a prevailing law or regulation. If a laboratory is cited for a deficiency and it can demonstrate to the satisfaction of the CLA that compliance would contravene a prevailing law or regulation, it shall not be required to remedy the deficiency. The deficiency will be expunged as not applicable.

1.20 Eligibility of Laboratories

1.20.a. Except as indicated in 1.20.b., the College of American Pathologists will not inspect or accredit a laboratory that is not performing patient or client testing.

1.20.b. When applicable law requires a laboratory to be (1) licensed in order to commence performing testing and/or (2) accredited before a license is issued, the College will inspect the laboratory's facilities, policies, and procedures. If the laboratory is in compliance with applicable requirements, it will be accredited with probation. As a condition of the probation, the laboratory

will have a complete inspection conducted approximately three months after testing commences. The laboratory will be charged additional fees for the secondary inspection.

1.20.c. Not withstanding anything mentioned in this section or elsewhere in the policies, the College of American Pathologists will not inspect or accredit a laboratory whose testing menu and/or application of tests is substantially outside the College's areas of expertise.

1.21 Probation and Suspension of Accreditation

1.21.a. General

1.21.a.1. The Commission on Laboratory Accreditation, or the Executive Committee of the Commission, may place all or any section of a laboratory on probation in accordance with 1.21.b or may suspend the accreditation of all or any section of a laboratory in accordance with 1.21.c.

1.21.a.2. A decision to place a laboratory (or a section thereof) on probation or to suspend the accreditation of a laboratory (or a section thereof) will be promptly reported to the appropriate oversight agencies.

1.21.a.3. A decision to place on probation or to suspend may be appealed in the same manner as a decision to deny accreditation (see 1.08 Denial of Accreditation).

1.21.a.4. As a condition of accrediting a laboratory or a laboratory section that has been placed on probation or that has been suspended, the Commission may require the laboratory to undergo, and to pay for, an inspection (which may be announced or unannounced) to determine whether the issues that led to the probation or suspension have satisfactorily been resolved. The Commission may also require the laboratory to submit whatever additional documentation the Commission (or Executive Committee) deems necessary to determine whether such issues have been resolved.

1.21.a.5. If a probation or suspension is lifted, the Commission will promptly notify the appropriate oversight agencies.

1.21.b. Probation

1.21.b.1. The Commission (or Executive Committee) may place a laboratory on probation if any of the following conditions is present:

1. The facts surrounding the decision to accredit are sufficiently unclear that the Commission (or Executive Committee) is unwilling to grant accreditation, but the situation does not appear to pose a substantial risk of harm to patients or to laboratory personnel.

2. The Commission (or Executive Committee) wishes to monitor the progress of a laboratory in correcting a deficiency or deficiencies that do not appear to pose a substantial risk of harm to patients or to laboratory personnel.

3. The laboratory has engaged in conduct contrary to the policy of the Commission, but such conduct is not sufficient to warrant denial, revocation, or suspension of accreditation.

4. The Commission (or Executive Committee) has denied or suspended the accreditation of specific sections of a laboratory.

1.21.b.2. The Commission (or Executive Committee) may place a section of a laboratory on probation if the conditions specified in 1.21.b.1.1 or 1.21.b.1.2 are present with respect to that section.

1.21.b.3. A laboratory that is placed on probation may continue to provide testing as an accredited laboratory except with respect to any section of the laboratory whose accreditation has been suspended.

1.21.b.4. A laboratory (or section thereof) that is on probation will remain on probation until the Commission (or Executive Committee) determines to deny or suspend accreditation — or to lift the probation and accredit the laboratory (or section thereof).

1.21.c. Suspension

1.21.c.1. The Commission (or Executive Committee) may suspend the accreditation of a laboratory if either of the following conditions is present:

1. The Commission (or Executive Committee) believes that the laboratory has:
    a. Deficiencies that may pose a substantial risk of harm to patients or to laboratory personnel — and either needs time to evaluate the situation further, or
    b. Concludes that the deficiencies can be corrected within a specified period of time.
2. The laboratory has failed to enroll in an approved proficiency testing program, has had proficiency testing results reported that the Commission (or Executive Committee) deems unreliable, or has failed to meet proficiency testing performance criteria.

1.21.c.2. The Commission (or Executive Committee) may suspend the accreditation of a section of a laboratory if it finds that the risk of harm to patients or to laboratory personnel is confined to that section or if the failure to meet proficiency testing performance criteria is confined to that section.

1.21.c.3. A laboratory (or section thereof) whose accreditation is suspended may not continue to provide testing as an accredited laboratory.

1.21.c.4. A laboratory (or section thereof) whose accreditation has been suspended will not be accredited until the Commission (or Executive Committee) determines that the deficiency or deficiencies that caused the suspension have been satisfactorily corrected.

1.21.c.5. If a laboratory fails to demonstrate within a period deemed reasonable by the Commission (or Executive Committee) that it is satisfactorily addressing the deficiency or

deficiencies that caused the suspension, the accreditation of the laboratory will be revoked. Appropriate oversight agencies will be notified of revocation of accreditation.

1.22 Protection of Complainants or Whistle-Blowers

1.22. The Accreditation Committee may revoke the accreditation of, deny accreditation to, or take such other action as it deems appropriate with respect to any laboratory that, directly or indirectly, threatens, intimidates, or retaliates against any individual for disclosing, or considering the disclosure of, information that might bear on the accreditation status of that laboratory.

1.23 Misrepresentation by a Participating Laboratory

1.23.a. The Commission on Laboratory Accreditation may revoke the accreditation of, deny accreditation to, or impose other sanctions against any laboratory that makes a misrepresentation relating to the Laboratory Accreditation Program.

1.23.b. A misrepresentation for purposes of this section includes, but is not limited to, a false statement of fact about the laboratory or its operations; fabrication or alteration of information, records or other documentation; failure to advise the Commission of facts or developments that may bear on the Commission's evaluation of the laboratory; and misstatement of the accreditation status of the laboratory. A misrepresentation may be in writing, oral, or through failure to provide material information.

1.24 Investigations and Media Attention

1.24.a. A laboratory must notify the College as soon as it finds itself to be the subject of an investigation by a state or federal agency or by another accreditation organization.

1.24.b. A laboratory must notify the College as soon as it finds itself to be the subject of adverse media attention.

1.24.c. A laboratory must notify the College if it discovers actions by laboratory personnel that violate federal, state, or local laws that regulate laboratories.

1.24.d. The laboratory must provide copies of the agency's correspondence and, as appropriate, reports, or, in the case of adverse media attention, a written summary of the allegations.

1.24.e. The laboratory must provide written documentation of any actions that have been taken or are planned.

1.24.f. The College will investigate an incidence of an investigation by a state or federal agency or by another accreditation organization or adverse media attention like a complaint (see 1.17 Investigation of Complaints.)

2. INSPECTION

2.01 Conflicts of Interest

2.01.a. Accreditation must be carried out in an impartial and objective manner, uninfluenced by any personal, financial, or professional interest of any individual acting on behalf of the CAP Laboratory Accreditation Program. To that end, the following prohibitions apply:

2.01.a.1. No inspector may be engaged in a close personal, family, business, or professional relationship with any personnel in a laboratory that the inspector inspects.

2.01.a.2. No inspector may solicit or accept, and no inspected laboratory or its parent institution or associated entity may offer or provide cash or non-cash gifts of any type, including personal gifts, products, services, or entertainment provided at no cost or unreasonably discounted cost.

2.01.a.3. No inspector may either formally or informally discuss, solicit, or accept, and no inspected laboratory or its parent institution or associated entity may either formally or informally discuss, offer to provide or provide, an employment or consulting arrangement, referral of business, or other business opportunity.

2.01.b.1. Prior to finalization of an inspector assignment, every inspector must disclose to the Assigning Commissioner any facts or relationships that are inconsistent with the above prohibitions, and any other potential conflicts of interest.

2.01.b.2. The above prohibitions shall apply through the course of the inspection and until 75 days from the date of the inspection.

2.01.c.1. An inspector who is found to have violated one of the above prohibitions shall be referred to the Executive Committee of the Commission and may be subject to sanctions, including loss of eligibility to serve as a CAP LAP inspector.

2.01.c.2. A laboratory, or its parent institution or associated entity, that is found to have violated one of the above prohibitions shall be referred to the Executive Committee of the Commission for investigation and may be subject to sanctions including requiring the laboratory to undergo and to pay for an additional inspection (which may be announced or unannounced); refusal to process accreditation reapplications; probation or suspension of accreditation; or denial or revocation of accreditation. Any impact on the accreditation decision will be referred to the Accreditation Committee.

2.02 Size and Composition of Inspection Team

2.02.a. The inspection team leader, in conjunction with LAP staff, shall determine the size and composition of the inspection team.

2.02.b. Each inspector is obligated to act in an unbiased and objective manner when conducting a laboratory inspection. If an inspection team member works for or otherwise has a direct reporting relationship to the team leader or another team member, both individuals should be cautious to retain objectivity in fact finding throughout the inspection process.

2.03 Non-routine Inspections

2.03.a. The Commission on Laboratory Accreditation or the Accreditation Committee may require a non-routine inspection, if there is evidence to indicate that the laboratory may be out of compliance with the Standards for Laboratory Accreditation. Such an inspection may focus on the area(s) suspected to be out of compliance with the *Standards*, but could also involve the entire laboratory and all its subspecialty areas. The inspection may be announced or unannounced.

2.04 Laboratory Self-Evaluations

2.04.a. Laboratories enrolled in the Accreditation Program must perform a self-evaluation in interim years.

2.04.b. Laboratories shall prepare a list of deficiencies identified during the course of the self-evaluation and document corrective action when deficiencies are noted.

2.04.c. The list of deficiencies, if any, identified during the course of the self-evaluation and documentation of corrective action(s) shall be made available to the Inspection Team Leader at the next on-site inspection.

2.04.d. Laboratories must notify the College when they have completed their interim inspections.

2.04.e. Failure to notify the LAP that the interim self-inspection has been completed may result in revocation of accreditation.

2.05 Confidentiality of Inspection Findings

2.05.a. Inspection findings are intended to be confidential. Inspectors should limit discussion of inspection findings to the context of the inspection in which they are made. Inspectors should disclose inspection findings only to individuals or entities associated with the inspection process, unless appropriate documented consent has been obtained for their release to others.

2.06 Appeal of Inspector Assignments

2.06.a. Announced Inspections: If the laboratory to be inspected has justifiable reason/just cause to believe that the named inspector cannot perform without bias, the laboratory may request appointment of a different inspector within 30 days of assignment. A laboratory may appeal an inspector assignment in writing first to the Assigning Commissioner, then to the appropriate Regional Commissioner, and finally to the Chair of the Commission on Laboratory Accreditation (CLA) if it believes that it cannot receive an objective inspection.

2.06.b. Unannounced Inspections: If the laboratory to be inspected has justifiable reason/just cause to believe the inspection team that has arrived cannot perform the inspection without bias, the laboratory should contact the CAP directly to receive instruction.

Explanatory note: Competition between a laboratory (or its parent institution) providing an inspection team and the laboratory (or its parent institution) to be inspected does not itself represent conflict of interest. The College of American Pathologists believes that, in such circumstance, team leaders and inspectors will conduct the inspection professionally and in an objective manner.

The CAP believes that the review of the inspection findings and the laboratory's responses to the cited deficiencies by the Reviewing Commissioner ensures an appropriately objective accreditation decision.

2.07 Use of Checklists

2.07.a. At least one Discipline-specific Checklist for each Discipline in which a laboratory offers patient testing must be used to conduct a routine or self inspection.

2.08 Source of Inspection Team

2.08.a. The Inspection Team Leader for a laboratory must not be in a business, professional, or personal relationship that would preclude an objective inspection.

2.08.b. A laboratory should not serve as the source of Inspection Team Leader (or team members) for the inspection of the laboratory that provided the Inspection Team Leader (and team members) for its immediate past inspection.

2.08.c. A laboratory should not serve as the source of Inspection Team Leader (or team members) for the inspection of the same laboratory for two consecutive on-site inspections.

2.09 Intentionally left blank

2.10 Routine Inspections

2.10.a. Except as noted in 2.10.c, routine inspections will be conducted within the six-month period prior to the laboratory’s anniversary date. Laboratories will not be informed of the inspection date.

2.10.b. Laboratories subject to unannounced inspections will not be informed of the identity of the inspection team members prior to the inspection.

2.10.c.1. Initial accreditation inspection dates will be announced.

2.10.c.2. International laboratory inspections, excluding Canadian laboratory inspections, should occur within the 30 days prior to the anniversary date and will be announced.

2.10.c.3. Reproductive Laboratory Accreditation program inspections should occur within the 30 days prior to the anniversary date and will be announced.

2.10.c.4. Forensic Urine Drug Testing Accreditation program inspections should occur within the 30 days prior to the anniversary date and will be announced.

3. INSPECTORS

3.01 Reimbursement of Travel Expenses

3.01.a. Travel arrangements must be made through the CAP Travel Desk if any air travel is required.

3.01.b. Hotel reservations must be made through the CAP Travel Desk if more than 10 hotel nights are involved.

3.01.b. An inspection team may use a charter flight when inspecting facilities not readily accessible by scheduled commercial carriers and when the cost of the flight compares favorably with costs that would have been incurred using scheduled commercial carriers. In such instances, the flight must be approved in advance and a special "charter flight" expense sheet must be completed.

3.01.c. The Chair of the CLA must review unusual requests for reimbursement.

3.02 Inspector Team Leaders, Inspectors, and Inspection Team Composition

3.02.a. Inspection Team Leaders may be appointed by Assigning or Reviewing Commissioners, and the Chair and Vice Chair of the Commission, and by LAP staff with oversight by the Commission.

3.02.b.1. Pathologist Inspection Team Leader. Whenever practical the Inspection Team Leader shall be a Board-certified pathologist and preferably affiliated with a College-accredited laboratory.

3.02.b.2. Non-pathologist Inspection Team Leader. A non-pathologist laboratory director may be an Inspection Team Leader. However, in those instances in which the laboratory offers services in either anatomic or cytologic pathology, the inspector for Anatomic Pathology must be a Pathologist, or a technologist under the direct supervision of a Pathologist, and the inspector for Cytopathology must be a Pathologist or Cytotechnologist who is actively engaged in the practice of Cytopathology.

3.02.b.3. Staff Inspector Inspection Team Leader. A Medical Technologist with expertise in the area to be inspected may be an Inspection Team Leader.

3.02.c. Inspection Team Members. Inspection team members may include pathologists, residents in pathology, clinical scientists, medical technologists, computer specialists, and others, as appropriate.

3.02.d.1. Assignment of Inspection Team Leaders. Assigning Commissioners wishing to assign an Inspection Team Leader from another State, Division, or Region must contact the Assigning Commissioner for that State, Division, or Region prior to the assignment.

3.02.d.2. Assignment of Inspection Team Leaders. When necessary to avoid conflicts of interest, the Chair will act as Assigning and Reviewing Commissioner for the laboratories associated with Reviewing Commissioners and the Vice Chair. The Vice Chair will act as Assigning and Reviewing Commissioner for the Chair's laboratory.

3.03 **Inspector Training Requirements**

3.03.a.1. Inspection team leaders must successfully complete training as specified by the Commission on Laboratory Accreditation within the two years prior to leading an inspection team.

3.03.a.2. All team leaders, including individuals who may have participated in an inspection as a team member, must successfully complete training and demonstrate competency in the following content:

- Core program information (including CAP standards and CLIA requirements)
- Team leader responsibilities
- Inspection techniques
- Other elements as designated by the Commission on Laboratory Accreditation

3.03.a.3. Trained team leaders must demonstrate competency or repeat training in the content described in 3.03.a.2, and participate in a training activity that covers changes to the Laboratory Accreditation Program since the previous training.

3.03.b.1. Inspection team members must successfully complete training as specified by the Commission on Laboratory Accreditation within the two years prior to conducting an inspection.

3.03.b.2. All team members must successfully complete training and demonstrate competency in the following content:

- Core program information (including CAP standards and CLIA requirements)
- Team member responsibilities
- Inspection techniques
- Other elements as designated by the Commission on Laboratory Accreditation

3.03.b.3. Trained team members must demonstrate competency or repeat training in the content described in 3.03.b.2, and participate in an activity that covers changes to the Laboratory Accreditation Program since the previous training.