



COLLEGE of AMERICAN
PATHOLOGISTS

CAP Accreditation and Mohs Surgery Laboratories

American Society of Mohs Histotechnology
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Agenda

- **CLIA and Accreditation overview**
- **CAP overview**
- **Accreditation goals and objectives**
 - **Terms of Accreditation**
 - **Laboratory Accreditation Manual**
 - **Standards**
 - **Checklists**
- **Checklists for the Mohs surgery laboratory: Laboratory General, All Common, Anatomic Pathology, Team Leader Assessment of Director and Quality**
- **Deficiencies**
- **Timelines**
- **Preparation for Inspection**
- **Questions**

CLIA and Accreditation Overview

- **Clinical Laboratory Improvement Amendments (CLIA)**
- **Originally passed in 1988, with subsequent amendments**
- **Clinical laboratories must be licensed by the federal government**
- **Continual accreditation to ensure compliance with all regulations placed under the responsibility of the Centers for Medicare and Medicaid Services (CMS)**

CMS Oversight

- **CMS delegated “deemed status” for accreditation to various organizations including:**
 - **The College of American Pathologists (CAP) – hospital, commercial, and military laboratories**
 - **The Joint Commission (JC) – hospital laboratories**
 - **The Commission on Laboratory Accreditation (COLA) – office-based laboratories**
 - **AABB – blood banks**
 - **Others**

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CAP Overview

- **Established in 1946**
- **Leading organization for board-certified pathologists**
- **More than 18,100 members and 600 employees**
- **Largest laboratory accrediting organization in the world**
- **Headquarters: Northfield, Illinois;**
Advocacy office in Washington, DC

CAP Overview continued

- **Advocating high quality and cost-effective patient care**
- **Global leader in laboratory quality assurance**
 - **Offering laboratory accreditation since 1963**
 - **More than 7,700 CAP-accredited laboratories in 50 countries**
 - **Estimated 22,000 laboratories in 90 countries enrolled in the CAP's proficiency testing (PT) programs**

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CAP Laboratory Accreditation Program: Its principles ensure consistent practice

CAP Philosophy

- **Any test worth doing is worth doing well with same quality assurance mechanisms to ensure consistent delivery of accurate, effective results in a physically safe environment.**
- **Quality improvement and continuous compliance is fundamental**
- **Qualified personnel and ongoing education required**
- **Accreditation program is based on peer review by active laboratory professionals**

CAP Laboratory Accreditation Program

Sets high standards for clinical, anatomic, and specialty laboratories that address quality, efficiency, and safety:

- **Exceeds U.S. Federal Government (CMS) regulatory requirements**
- **Provides a solid foundation for quality practices**
- **Leads in developing requirements for molecular oncology, cytogenetics, and reproductive medicine**
- **Global Reach: the CAP accredits laboratories in 50 countries**

CAP Laboratory Accreditation Program: Value of Peer-Based Inspections

- **Laboratory professional (pathologist, technologist, etc.)**
 - Gains insight through interacting with peer professionals
 - First-hand knowledge to offer constructive feedback
- **Promotes continuous education and continuous improvement**
- **Inspectors with specialty expertise**
- **Working professionals exposed to new technologies**

Terms of Accreditation

- **Laboratory must inform the CAP when there is a change in director, name, test menu, location, ownership**
- **Laboratory must inform the CAP when it is the subject of an investigation by the State or CMS or when there is adverse publicity**
- **Laboratory must agree to be inspected on-site every two years and must provide an inspection team of comparable size when asked.**

Laboratory Accreditation Manual

Provides comprehensive overview of the CAP's Laboratory Accreditation Program, including:

- **CAP accreditation governance structure**
- **Commissioners**
- **Inspectors and CAP staff**
- **Documents**
- **Standards**
- **Checklists**
- **Philosophies**
- **Application Process**
- **Inspection Cycle**
- **How to inspect**
- **Policies**

CAP Standards for Laboratory Accreditation

- **The Standards constitute the core principles of the CAP's Laboratory Accreditation Program**
- **The Standards' objective is to ensure that accredited clinical laboratories meet the needs of patients, physicians, and other health care practitioners.**
- **The CAP accredits clinical laboratories that conform to the standards.**

CAP Standards for Laboratory Accreditation

- **The specifics of how the standards are applied to laboratories are found in the CAP Accreditation Checklists and Terms of Accreditation.**
- **The CAP is committed to helping laboratories comply with the standards through peer-based education.**
- **The ultimate responsibility for compliance rests with the laboratory director and laboratory organization.**

CAP Standards for Laboratory Accreditation

Standard I – Director and Personnel

- **A board-certified pathologist or other qualified physician or scientist with doctoral-level or commensurate qualifications that meet or exceed requirements or applicable law shall direct the laboratory service.**
- **The director must be qualified to assume professional, scientific, consultative, organizational, administrative, and educational responsibilities for the services provided.**

CAP Standards for Laboratory Accreditation

Standard I – Director and Personnel (continued)

The director is responsible for maintaining the Standards and implementing the requirements of the Accreditation Checklists and documenting compliance.

CAP Standards for Laboratory Accreditation

Standard II – Physical Resources

- **There shall be sufficient resources to support the activities of the laboratory.**
- **Such resources include, but are not limited to, physical space, testing instruments, reagents, information processing and communication systems, ventilation, storage and waste disposal facilities, and public utilities.**

CAP Standards for Laboratory Accreditation

Standard II – Physical Resources (continued)

- **Patients, laboratory personnel, and visitors shall be protected from hazardous conditions.**
- **Reasonable accommodation shall be made for disabled persons.**

CAP Standards for Laboratory Accreditation

Standard III – Quality Management

The laboratory shall have policies and procedures to ensure quality laboratory testing and patient safety, including, but not limited to:

- Validation of test systems
- Analytic quality control
- Quality management of pre- and postanalytic processes
- Proficiency testing (PT)/External Quality Assurance (EQA) (or periodic alternative)
- Human resource management
- Information management
- Ongoing quality improvement
- Appropriate communication to clinicians, patients, administration, and government entities

CAP Standards for Laboratory Accreditation

Standard IV – Administrative Requirements

- **CAP-accredited laboratories must comply with the requirements specified in the Accreditation Checklists and Terms of Accreditation.**
- **These requirements include, but are not limited to:**
 - **On-site inspections**
 - **Interim self assessment**
 - **Non-routine inspections**
 - **Maintenance of appropriate records**
 - **Cooperation with the Laboratory Accreditation Program and adherence to its policies**

Accreditation Checklists

- **The CAP program is based on rigorous accreditation standards that are translated into detailed checklist requirements.**
- **CAP inspection teams use the checklists, a quality practice blueprint for laboratories, as a guide to assess the laboratory's overall management and operation.**
- **The CAP releases a new edition annually, usually in late July.**

Accreditation Checklists

- **Laboratory General**
 - **All Common**
 - **Team Leader Assessment of Director and Quality**
 - **Anatomic Pathology**
 - **Biorepository**
 - **Chemistry and Toxicology**
 - **Clinical Biochemical Genetics**
 - **Cytogenetics**
 - **Cytopathology**
 - **Flow Cytometry**
 - **Hematology and Coagulation**
 - **Histocompatibility**
 - **Immunology**
 - **Limited Service Laboratory**
 - **Microbiology**
 - **Molecular Pathology**
 - **Point-of-Care Testing**
 - **Transfusion Medicine**
 - **Urinalysis**
- Checklists in **blue** apply to Mohs surgery laboratories

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Accreditation Checklists: Laboratory General

General topics:

- **Quality Management**
- **Specimen Collection, Data Handling, Result Reporting**
- **Laboratory Computer Services**
- **Personnel**
- **Physical Facilities**
- **Laboratory Safety**

Deficiencies

Each checklist requirement bears a designation of Phase I or Phase II.

- **Phase I: These requirements compromise the quality of the services without endangering the health and safety of patients, clients, or personnel. If a laboratory is cited with a Phase I deficiency, correction and a written response to the CAP are required, but supporting documentation is not required.**

Deficiencies continued

- **Phase II: Requirements may have a serious impact on quality of services or may endanger the health and safety of patients, clients, or personnel. All Phase II deficiencies must be corrected before the CAP Accreditation Committee grants accreditation. Correction requires that the laboratory provide to the CAP both a plan of action and supporting documentation that the plan has been implemented.**

Accreditation Checklists: Laboratory General continued

GEN.16902 QM Implementation

Phase II

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

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

Evidence of Compliance:

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

Accreditation Checklists: All Common

General Topics:

- **Proficiency Testing**
- **Quality Management**
- **Procedure Manual**
- **Results Reporting**
- **Reagents**

Accreditation Checklists: All Common

General Topics (continued):

- **Instruments and Equipment**

- Instrument and equipment maintenance/ function checks
- Thermometers
- Temperature-dependent instruments, equipment, and environments

- **Test Method Validation/Verification**

- Method performance specifications
- Reference intervals

Accreditation Checklists: All Common

COM.04200 Instrument/Equipment Record Review Phase II

Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the laboratory director or designee.

Accreditation Checklists: All Common

COM.30300 Reagent Labeling

Phase II

Reagents, calibrators, controls, and solutions are properly labeled, as applicable and appropriate, with the following elements.

1. Content and quantity, concentration or titer
2. Storage requirements
3. Date prepared or reconstituted by laboratory
4. Expiration date

NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

Accreditation Checklists: Team Leader Assessment of Director and Quality Checklist (TLC)

Laboratory Director Assessment

- **Qualifications and General Requirements**
- **Laboratory Director Responsibility and Oversight**
- **Laboratory Director not on site full time.**

Accreditation Checklists: Team Leader Assessment of Director and Quality Checklist

TLC.10440 Effective QM Phase II

The laboratory director ensures an effective quality management program for the laboratory.

NOTE: The laboratory director must be involved in the design, implementation and oversight of the laboratory's quality management program.

Accreditation Checklists: Team Leader Assessment of Director and Quality Checklist

TLC.10440 Effective QM Phase II (continued)

Evidence of Compliance:

- *Written QM plan covering all areas of the laboratory AND*
- *Records documenting the laboratory director approval of the QM plan and the selection of quality indicators AND*
- *Records (eg, reports, QM meeting minutes) documenting laboratory director review of quality indicators, annual assessment of QM plan, complaints, and incidents with development and implementation of plans of corrective action*

Accreditation Checklists: Team Leader Assessment of Director and Quality Checklist

TLC.11425 Director Responsibility - Delegation of Functions Phase II

If the laboratory director has delegated some functions to others, documentation specifies the individuals and the specific activities so authorized.

NOTE: 1) Delegation of functions must be in writing. 2) The laboratory director is responsible for ensuring that delegated functions are properly carried out. 3) It is the responsibility of the laboratory director to ensure that persons performing delegated functions are qualified to do so.

Accreditation Checklists: Team Leader Assessment of Director and Quality Checklist

TLC.11425 Director Responsibility - Delegation of Functions Phase II (continued)

Examples of items that may be delegated include review of QC data, proficiency testing performance, and test methodology. Some functions may not be delegated including provision of appropriately trained supervisory and technical staff and the identification of their responsibilities.

The laboratory director must document personal, onsite assessment of physical and environmental conditions and the adequacy of staffing.

Accreditation Checklists: Anatomic Pathology

Anatomic Pathology Checklist



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Phase I Deficiencies: Examples

ANP.12075 Residual Frozen Tissue Phase I

Following frozen section examination, the residual frozen tissue is routinely processed into paraffin, and a histologic section prepared and examined for comparison with the frozen section interpretation. ***NOTE: The laboratory must prepare a paraffin block and stained slide(s) from each frozen section block, and such paraffin blocks must be retained in accordance with CAP guideline for retention of surgical pathology blocks (ANP.12500).***

Correlation of frozen section findings with a permanent section prepared from routinely fixed and processed residual frozen tissue is an important quality improvement mechanism. Evaluation of such permanent sections provides important feedback on the accuracy of frozen section diagnoses and improves recognition of specific frozen section morphologic alterations.

Phase I Deficiencies: Examples

ANP.12075 Residual Frozen Tissue Phase I (continued)

The only exceptions to this requirement are as follows: 1) Frozen tissue that must be submitted for specialized studies; 2) Mohs frozen sections. However, the CAP strongly recommends preparation of paraffin sections from frozen tissue used for Mohs frozen sections, for quality management purposes. CAP also recommends retention of the tissue used for Mohs frozen sections in accordance with CAP retention guidelines.

Evidence of Compliance: Written procedure for the processing and examination of residual frozen tissue including correlation of the findings

Phase II Deficiencies: Examples

ANP.11650

Mohs Diagnosis

Phase II

Mohs surgically excised tissue diagnoses are made by a dermatologist, dermatopathologist, or pathologist.

Note: The diagnosis includes whether or not the tumor is present.

ANP.12173

Mohs Report

Phase II

There is a written report generated for each Mohs surgical procedure.

Note: A written note, report, or diagram must be included in the patient's medical record or operative report. The report should include required elements such as gross description, accession number, designation of relationships of blocks to the slides, and clear diagnosis on each specimen.

Phase II Deficiencies: Examples

ANP.10050

Previous/Current Material Review Phase II

Whenever appropriate, pertinent previous cytologic and/or histologic material from the patient is reviewed with current material being examined.

Note: Because sequential analysis of cytologic and histologic specimens may be critical in patient management and follow-up, efforts must be made to routinely review pertinent previous material. Documentation of the retrospective review should be included in the current patient report.

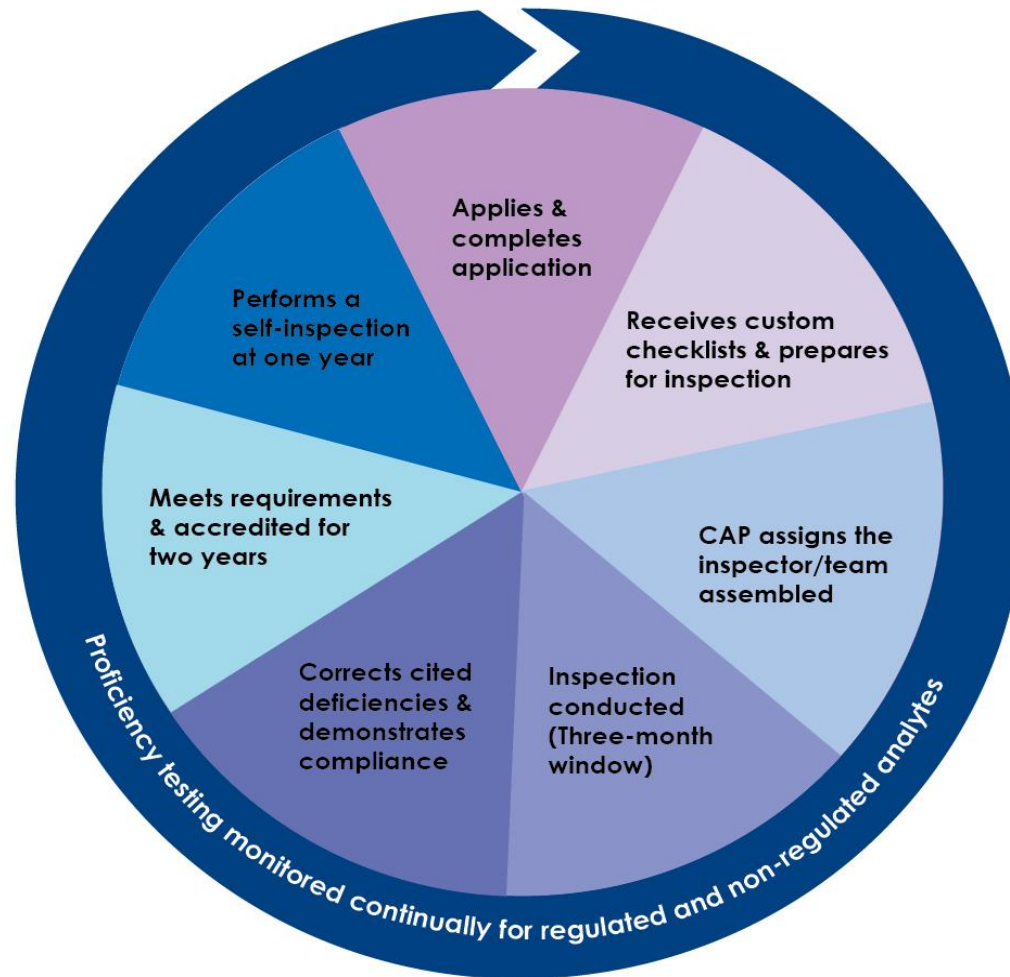
Most Common Deficiencies: Mohs Surgical Laboratories

- **Incomplete personnel folders (e.g. missing diplomas or transcripts)**
- **Lack of an organized competency program**
- **Missing two identifiers on slides**
- **Lack of an organized quality management program or not implemented as designed.**
- **Document control issues (e.g. policies/procedures for all activities, not approved by director prior to implementation and/or not reviewed biennially or annually.)**

Challenging a Deficiency

- **When submitting the documentation to correct any deficiencies, the laboratory has the right to challenge a deficiency if it feels that the deficiency was cited inappropriately or incorrectly.**
- **Laboratory must state that the deficiency is being challenged and submit supporting documentation to prove it was in compliance at the time of the inspection or indicate if the deficiency was cited inappropriately, e.g. for a procedure that is not part of the test menu.**

CAP Laboratory Accreditation Program: Two-Year Cycle



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Inspection Preparation

- **Review Table of Organization**
- **Review Checklists**
 - **Requirements and notes**
 - **Evidence of compliance**
- **Annotate Checklists**
 - **Notes**
 - **Excel Spreadsheet online**
 - **Records and examples**

Inspection Preparation (continued)

- **Have available for the inspection**
 - **QM plan and meeting minutes**
 - **Personnel folders containing education records (i.e. diploma or transcript), previous experience, job description, competency evaluations, and continuing education activities**
 - **Procedure manual**
 - **Daily temperature and maintenance records for the cryostat and any other equipment plus the cryostat decontamination schedule and record**

Inspection Preparation (continued)

- **Conduct a Mock Inspection**
 - **Involve all staff**
 - **Switch roles**
 - **Locate and review all required records, personnel files**
 - **“Cite” deficiencies**

Need more information?

- Email: accred@cap.org
- Phone: 800-323-4040



Questions





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