



COLLEGE of AMERICAN
PATHOLOGISTS

Program Policies

CAP 15189 Accreditation Program



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1 Scope

The CAP 15189 Accreditation Program policies govern the CAP 15189 Accreditation Program (CAP 15189 Program) of the College of American Pathologists (CAP).

2 References

Application of this document and government of the program take into consideration the following related documents:

CAP Accreditation Programs Policy Manual Version 2017.12.09, CAP Operating Policies and CAP Public Policies

CLSI Harmonized Terminology Database: <http://htd.clsi.org/>

ISO 15189:2012 Medical laboratories—Requirements for quality and competence

ISO 17011:2017 Requirements for accreditation bodies accrediting conformity assessment bodies

ISO 19011:2018 Guidelines for auditing management systems

ISO/IEC 9000:2015 Quality management systems—Fundamentals and vocabulary

ISO/IEC 17000:2004 Conformity assessment—Vocabulary and general principles

ISO/IEC 17043:2010 Conformity assessment—General requirements for proficiency testing

3 CAP 15189 Accreditation Program

3.1 Administration and Oversight

3.1.1 The CAP 15189 Program is administered by CAP management in collaboration with the CAP 15189 Committee (CAP 15189C). The CAP 15189C oversees program policies, CAP conditions of participation, and accreditation program decisions.

3.1.2 The committee is subject to oversight by the Council on Accreditation (Council) of the CAP. The Council reports to the CAP Board of Governors.

3.2 Program

3.2.1 CAP 15189C applies ISO 15189 (Medical Laboratories—Requirements for quality and competence) to those laboratories that voluntarily determine to participate in the program and that the CAP determines to be eligible for participation.

3.2.2 CAP 15189C and the other parts of the CAP that are involved with the CAP 15189 Program strive to administer the program in a fair, impartial, and nondiscriminatory manner.

3.3 Personnel

3.3.1 The CAP establishes requirements for competency for all personnel involved in the CAP 15189 Program. Personnel involved in the program shall meet the requirements for competency for the functions they perform.

3.4 Relationship to Proficiency Testing Providers

3.4.1 The CAP 15189 Program is independent and separate from the governance of the providers of proficiency testing programs.

3.5 Documents

3.5.1 The CAP controls all documents and data related to the CAP 15189 Program.

3.5.2 The CAP 15189 Program maintains an electronic record system. The records shall be identified, managed, and disposed of in a manner designed to ensure integrity of the process and confidentiality of the information.



3.5.3 Records generated, collected, or utilized for the purpose of the CAP 15189 Program shall be kept at least six years after a laboratory ends participation.

3.6 Confidentiality

3.6.1 Information about a laboratory shall not be disclosed to a third party without written consent of the laboratory, except as required by law or elsewhere in this document. Where the law requires information to be disclosed to a third party, the laboratory shall be notified of the fact and extent of disclosure in a timely manner.

3.7 Consulting

3.7.1 The CAP shall provide any needed explanation of the ISO 15189 Standard to an applicant when the desired scope of accreditation is related to a specific CAP 15189 Program offering. Explanations of the standard shall be in general in nonprescriptive terms.

3.7.2 If a member of CAP 15189C or CAP personnel provided consulting services in the past to an applicant or client laboratory for the purposes of CAP 15189 accreditation, the individual shall formally declare a conflict of interest with that specific organization and withdraw from the assessment process and accreditation decision related to subject laboratory.

3.7.3 Educational offerings by the above-named parties related to increasing the general understanding of the CAP 15189 Program and the intent of the accreditation requirements in ISO 15189 are acceptable and not considered to affect the confidentiality, objectivity, or impartiality of the program.

3.7.4 CAP staff shall not state or imply that accreditation would be simpler, easier, faster, or less expensive if a specific person or consultancy were used.

3.8 Fees

3.8.1 Fees are subject to change without notice.

3.8.2 Laboratories applying or reapplying for accreditation by the CAP 15189 Program shall furnish the full fees to the CAP at the time of application. The fees are nonrefundable.

4 Accreditation Process

4.1 Requirements and Scope

4.1.1 The ISO 15189 Standard forms the basis of the accreditation requirements. Interpretation and expectations of the accreditation requirements against which the laboratory is assessed are the responsibility of the CAP 15189C.

4.1.2 Each applicant and accredited laboratory shall make its records fully available to CAP 15189 Program staff in connection with the accreditation, annual surveillance assessments, and any follow up on complaints or new information about the laboratory.

4.1.3 Applicants and accredited laboratories are required to adhere to the College of American Pathologists policies of participation in proficiency testing.

4.1.4 The CAP shall give laboratories due notice of any changes to accreditation requirements and shall verify that each laboratory carries out the necessary adjustments to its procedures within a grace period defined for the purpose by the CAP 15189 Program.

4.2 Eligibility

4.2.1 To be eligible for CAP 15189 accreditation, a laboratory must (a) be a legal entity or part of a legal entity; (b) have a clearly defined and documented scope of services; (c) offer services within the scope of the ISO 15189 Standard, and d) be a participant in the CAP's Laboratory Accreditation Program.



4.3 Accreditation Cycle

4.3.1 Accreditation under the CAP 15189 Program consists of the following steps:

- Application and/or reapplication (required for each accreditation cycle)
- Submission of internal audit and management review reports by the laboratory
- Desk review of the laboratory's quality management system documents at the CAP
- Optional on-site gap assessment (initial accreditation cycle only)
- Optional on-site preassessment (initial accreditation cycle only)
- On-site accreditation assessment
- On-site surveillance assessment (one year after on-site accreditation assessment)
- On-site surveillance assessment (two years after on-site accreditation assessment)

4.3.2 Participation in the CAP 15189 Program is initiated by direct inquiry to the CAP. After establishing the laboratory's eligibility to participate in the program, the laboratory will be notified of applicable fees. If the laboratory wishes to participate, it shall submit an application with supporting documents and pay the fees in full. Fees are not refundable.

4.4 Assessment Team

4.4.1 The program manager will select and assign the assessment team. The team will include a lead assessor and at least one technical assessor. The responsibilities of the lead assessor include the oversight of the customer as an account executive including but not limited to the review of the internal audit and management review reports, completing the desk review, communicating with the laboratory, setting up an assessment agenda, managing the on-site assessments and related reports, reviewing Corrective Action Reports (CARs) and communicating the findings and recommendations to the CAP 15189C. The lead assessor is changed from the one accreditation cycle to the next cycle to mitigate bias in assessment recommendations.

4.4.2 The program manager shall inform the applicant of the names of the assessment team members in the application to allow the applicant to appeal the appointment of any particular assessor or expert on the basis of conflict of interest. The laboratory may appeal the appointment of any particular assessor or expert on the basis of conflict of interest within 30 days from the time of notification of the appointment upon acceptance to the program. The appeal must be submitted in writing or by email.

4.4.3 Individuals responsible for the accreditation decision shall not have participated as assessors in the on-site assessment of the laboratory.

4.5 Assessment Date

4.5.1 The assessment plan and a mutually agreeable date for the on-site assessment shall be set in communication with the applicant.

4.6 Gap Assessment and Pre-assessment (Initial Cycle)

4.6.1 CAP 15189 Program staff will work with the laboratory to help the laboratory prepare for the assessment process. The laboratory may elect to have a gap assessment and/or a preassessment performed by CAP 15189 Program staff, at additional cost, prior to the accreditation assessment.

4.6.2 A laboratory shall not experience any disadvantage if it does not participate in a gap or preassessment. No accreditation decision shall be based on specific findings from either the gap assessment or preassessment.



4.7 Accreditation Assessment

- 4.7.1 During the on-site accreditation assessment, the assessment team shall observe activities to which CAP 15189 accreditation requirements are applicable and that are within the scope of the laboratory application.

The applicant has the right to turn an accreditation assessment into a gap assessment if a gap has not already been conducted. Applicants may only turn an accreditation assessment into a gap assessment once.

4.8 Surveillance Assessments

- 4.8.1 At the conclusion of both the first and the second year after accreditation, the CAP 15189 Program staff will assess the continued conformance of the laboratory to the ISO 15189 standard through surveillance assessments. Emphasis will be placed on the management and technical elements of the ISO 15189 Standard, any outstanding issues or follow up to previous corrective actions, review of effectiveness, and review of annual internal audit and management review reports.
- 4.8.2 Experience gained during previous assessments shall be taken into account during surveillance assessments.
- 4.8.3 Nonconformities identified during surveillance assessments shall be addressed by the laboratory in the same way as those identified during accreditation assessments. Surveillance CARs will be exempt from committee review based on the assessment outcomes and with consideration to continual improvement performance.

4.9 Laboratory's Responsibilities to Address Nonconformities

- 4.9.1 Root Cause Analysis, as defined in the Terms and Definitions section, must be performed by the laboratory for all nonconformities with an investigation commensurate with the degree of the nonconformity and the level of risk.
- 4.9.2 CARs submitted by the laboratory to the CAP 15189 Program must contain a formulated corrective action and evidence of its implementation for each major nonconformity identified and a formulated corrective action plan for each minor nonconformity identified.

4.10 Findings Posing Immediate Jeopardy to Laboratory Personnel, Patients, or General Public

- 4.10.1 Findings during an accreditation assessment posing immediate jeopardy, as defined in the Terms and Definitions section, may be communicated by the CAP to other accreditation organizations or to regulatory bodies without undue delay. A laboratory reported to an accreditation organization or regulatory body due to an immediate jeopardy shall be copied on the notification.

4.11 Accreditation and Surveillance Decisions

- 4.11.1 After concluding review of accreditation or surveillance assessment findings and completion of CARs, CAP 15189 Program management will review documentation of the findings to verify completion of documentation and adherence to program policies. The lead assessor will submit a report to the CAP 15189C for accreditation decision.
- 4.11.2 Accreditation shall not be granted until a) all major nonconformities have corrective action plans and evidence of implementation submitted and reviewed by CAP 15189 Program personnel and accepted by the CAP 15189C (Acceptance may be through document review and/or on-site assessment/surveillance.); b) all minor nonconformities have corrective action plans that have been reviewed by program personnel through document review and accepted by the CAP 15189C; and c) all nonconformities have plans developed for reviewing the effectiveness of all corrective actions taken, as appropriate and as per laboratory documented procedure.



4.11.3 After each accreditation and surveillance assessment, one of the following accreditation or surveillance decisions is made by the CAP 15189 Program.

4.11.3.1 Accreditation decision: Accreditation

The laboratory will be accredited for a period of three years.

The anniversary date of the accreditation cycle shall be the final date of the on-site accreditation assessment.

4.11.3.2 Accreditation decision: Accreditation with Requirements

The laboratory will be Accredited with Requirements if the CAP 15189C concludes the laboratory does not pose a substantial risk of harm to laboratory personnel, patients, or the public, the laboratory is likely to come into compliance with the requirements of the ISO 15189 standard within a specified time frame, and that one or more of the following conditions is present:

- (1) Documentation submitted by the laboratory is insufficient to determine conformance with ISO 15189 and to assure sustained conformance, and the CAP 15189C wishes to monitor the laboratory's progress in correcting one or more of its nonconformities;
or
- (2) The laboratory has engaged in conduct contrary to the policies of the CAP 15189 Program but such conduct is not sufficient to warrant denial or revocation of accreditation.

In determining whether the requirements have been satisfied, the CAP 15189C may require the laboratory to undergo and pay for a non-routine on-site assessment. The CAP 15189C may also require the laboratory to submit whatever additional documentation and take whatever additional steps the CAP 15189C deems necessary to determine that the requirements have been satisfied.

If the laboratory fails to satisfy the applicable requirements within the specified time frame, the CAP 15189C may extend the time period for the laboratory to satisfy the requirements, suspend or revoke the accreditation, or take such other action as the CAP 15189C deems appropriate. In making its decision, the CAP 15189C shall determine the progress that has been made by the laboratory, how close the laboratory is to complying with the requirements of the ISO 15189 standard, and the risk of harm to laboratory personnel, patients, or the public.

A decision to grant accreditation with requirements is not subject to a petition for reconsideration or to any appeal.

4.11.3.3 Accreditation decision: Deny Accreditation

The laboratory will not be accredited.

A laboratory for which the accreditation decision "Deny accreditation" was rendered may seek reconsideration or appeal the decision (see 5.1-5.6).

4.11.3.4 Accreditation decision: Revoke Accreditation

The CAP 15189C may revoke accreditation of an accredited laboratory when it fails to meet the requirements of the Program. A laboratory for which the accreditation decision "revoke accreditation" was rendered may seek reconsideration or appeal the decision (see 5.1-5.6).



- 4.11.3.5 Surveillance decision: Continue Accreditation
The laboratory continues to be accredited.
The anniversary date of the accreditation cycle remains the final date of the on-site accreditation assessment.
- 4.11.3.6 Surveillance decision: Continue Accreditation With Requirements
The laboratory continues to be accredited, and the laboratory shall meet the requirements imposed by the CAP 15189C within the specified time frame, as described in 4.10.3.2.
- 4.11.3.7 Surveillance decision: Suspend Accreditation Until Requirements Met
The laboratory accreditation to the ISO 15189 standard will be temporarily lifted until results of re-evaluation have been accepted by the CAP 15189C. Accreditation With Requirements will be suspended if documentation does not support conformance with ISO 15189 by the laboratory or when, in the judgment of the CAP 15189C, the nonconformance with one or more requirements has caused, or is causing, or is likely to cause, serious injury or is likely to lead to inappropriate medical care, harm, or death to individuals served by the laboratory, laboratory workers, or visitors; and/or poses a serious risk to the health and safety of the laboratory personnel, patients, or the public.

4.12 Denial and Revocation of Accreditation Independent of Accreditation or Surveillance Decisions

- 4.12.1 The CAP 15189C may deny or revoke accreditation of a laboratory when it fails to meet the requirements of the CAP 15189 Program.
- 4.12.2 Withdrawal or sanctioning of other laboratory certifications and accreditations may lead to denial or revocation of CAP 15189 accreditation.
- 4.12.3 Accreditation of a laboratory by this program will be revoked immediately if the CAP's Laboratory Accreditation Program accreditation is revoked.

4.13 Maintenance of Accreditation

- 4.13.1 The laboratory shall perform internal audits and management review of its quality management system at least annually. Documentation of these activities, including corrective actions, is subject to review by the CAP 15189C.
- 4.13.2 CAP 15189C may, after accreditation, impose requirements on an accredited laboratory, place an accredited laboratory on suspension, or revoke accreditation (a) if new developments or information cause it to conclude that the laboratory does not meet the requirements of the CAP 15189 Program, or (b) if the laboratory does not cooperate with the CAP 15189C or its personnel in the accreditation process or during subsequent evaluations.
- 4.13.3 Every complaint involving a CAP 15189-accredited laboratory will be investigated via Laboratory Accreditation Program Investigations staff and the Commission of Laboratory Accreditation Complaints and Investigations Committee.
- 4.13.4 The laboratory shall submit or make available to the CAP an internal audit and management review report at least annually.
- 4.13.5 On-site assessments (reassessments) may be conducted more frequently during the accreditation cycle if the assessors and CAP 15189C determine a need.



4.14 Changes in Status or Operation of Laboratory

4.14.1 CAP 15189-accredited laboratories and laboratories seeking accreditation shall inform the CAP within 30 days of changes in any aspects of their status or operation that affect their: (a) legal, commercial, or organizational status; (b) organization and management (key managerial staff); (c) significant policies or procedures affecting the operations of the accredited laboratory; (d) physical premises; (e) personnel, equipment, facilities, working environment, or other resources, where significant; (f) local certification; and (g) any other matters that may affect the laboratory's capability, scope of activities, or conformance with the requirements in this document or any other relevant criteria of competence specified by the accredited laboratory.

4.15 Change in Scope of Laboratory

4.15.1 In response to an application for amendment to the current scope of accreditation, CAP 15189 Program personnel shall decide what assessment, if any, is appropriate and make recommendations to the CAP 15189C.

4.15.2 CAP 15189C has final authority to approve any change to scope for an accredited laboratory. Requests for expansion of scope will, at a minimum, require a remote documentation review and may require on-site assessment and an adjustment in the fee schedule for that laboratory.

4.16 Accreditation Certificate

4.16.1 The CAP 15189 Program shall provide documentation of accreditation to the accredited laboratory in the form of a certificate signed by the chair of the CAP 15189C and the president of the CAP. The certificate shall identify the scope covered by the accreditation, effective date of the accreditation, and length of the accreditation period, including the date of expiration.

4.17 Reference to Accreditation Status

4.17.1 The CAP is the owner of the CAP 15189 accreditation mark.

4.17.2 The accreditation mark is intended for use exclusively under the CAP 15189 Program and shall be used only in accordance with the CAP mark guidelines.

4.18 Directory of Accredited Laboratories

4.18.1. The CAP shall maintain and publish a directory of laboratories accredited by the CAP 15189 Program, including their locations and a description of the scope of accreditation granted and effective dates of their accreditation.

5 Appeals, Complaints, and Disputes

5.1 Denial, Suspension, or Revocation

5.1.1 A laboratory that has its accreditation denied, suspended, or revoked shall be notified by express delivery. The notification shall briefly state the reason(s) for the determination.

5.2 Reconsideration

5.2.1 A laboratory that has its accreditation denied, suspended, or revoked may seek reconsideration by the CAP 15189C based on information that it presents to the CAP 15189C within 30 days after notification of the decision. CAP 15189C shall determine whether to invite representatives of the laboratory, at the laboratory's expense, to appear before the committee and whether to seek additional information. After the committee has heard any presentation by representatives of the laboratory, it shall excuse those representatives. It shall make its decision on reconsideration based on all



the facts presented. It shall notify the laboratory by express delivery promptly after it has made its decision. If the decision is adverse to the laboratory, the notification shall briefly state the reason(s) for the decision.

5.3 Appeal

- 5.3.1 A laboratory that has its accreditation denied, suspended, or revoked may appeal the decision to the Council on Accreditation within 30 days after notification of the decision. A laboratory is not required to seek reconsideration prior to an appeal. However, a laboratory that files a request for reconsideration may not file an appeal to the council until 30 days following the denial of reconsideration.
- 5.3.2 The council shall consider a properly filed appeal at its next scheduled meeting occurring no less than 30 days following receipt of the appeal.
- 5.3.3 The council shall determine 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 council members. If the council determines to invite such representatives, it shall promptly notify the laboratory. The Council may also seek input from the chair of CAP 15189C or the chair's designee.
- 5.3.4 After the council has heard any presentation by representatives of the laboratory and/or by representatives of CAP 15189C, it shall excuse those representatives. It shall make its decision on appeal based on all the facts presented. 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.
- 5.3.5 The council shall notify the laboratory and CAP 15189C of its decision on appeal by express delivery or email promptly after it has made its decision. The notification shall briefly state the reason(s) for the decision.

5.4 Stay of Decision

- 5.4.1 Neither a request for reconsideration to the CAP 15189C nor appeal to the Council on Accreditation shall stay the initial decision from which reconsideration or an appeal is sought.

5.5 Reinstatement

- 5.5.1 If a denial, suspension, or revocation of accreditation is reversed on reconsideration or appeal, the laboratory's accreditation shall be reinstated.

5.6 Reapplication

- 5.6.1 A laboratory that has accreditation denied or revoked may not reapply for accreditation until six months from the date of the notification of denial or revocation has elapsed.



- 5.6.2 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.

6 Terms and Definitions

For the purposes of this document and in the context of the CAP 15189 Program, the following terms and definitions apply.

- 6.1 CAP 15189**
Name used to refer to the CAP 15189 Accreditation Program.
- 6.2 CAP 15189 Accreditation Program**
Program of the College of American Pathologists offering formal recognition that a medical laboratory fulfills the requirements for quality and competence as outlined in the ISO 15189 Standard.
- 6.3 CAP 15189 Committee (CAP 15189C)**
Group of individuals within the College of American Pathologists charged with ensuring objectivity and consistency in the College of American Pathologists ISO accreditation decision making. This committee also oversees the development of audit tools for ISO accreditation, supporting guidance documents and education materials for use by the auditor and participating laboratories, defines the policies and criteria for ISO 15189 accreditation, and makes accreditation and surveillance decisions for a laboratory.
- 6.4 Immediate Jeopardy**
Situation in which nonconformity with one or more program requirements has caused, or is likely to cause serious injury, harm, impairment, or death to a person or persons.
- 6.5 ISO 15189**
Refers to the current published version of the ISO 15189 Standard as listed in the references.
- 6.6 Laboratory Accreditation Program**
If used in CAP documents, this term refers to the CAP's Laboratory Accreditation Program which meets the requirements of the Clinical Laboratory Improvement Amendments (CLIA).
- 6.7 Major Nonconformity**
A major nonconformity is a nonconformity in which the laboratory is out of conformance with an accreditation requirement and for which the laboratory would need to make major adjustments to fulfill the requirement and thus be brought into conformance. A major nonconformity is present if one or more of the following are identified: (a) a practice or incident that poses a significant risk to impact adversely the health and safety of laboratory personnel, patients, or the public; or (b) more than one minor nonconformities against one requirement, indicating a breakdown of the system or an inability to establish confidence in the integrity of a process.
- 6.8 Minor Nonconformity**
A minor nonconformity is a nonconformity in which the laboratory is only partially out of conformance with the requirement and for which the laboratory would need to make minor adjustments to fulfill the requirement and thus be brought into conformance. A minor nonconformity is present if one or more of the following are identified: (a) a single, isolated incident arising in a system in which such isolated incident is unlikely to impact adversely the health of laboratory personnel, patients, or the public; (b) a practice that is inconsistently applied; (c) a practice that does not effectively comply with laboratory commitments provided in its own documentation; (d) an activity which could impart low risk to fulfilling an accreditation requirement.



6.9 Nonconformity

A nonconformity describes the situation in which the laboratory does not fulfill a specific accreditation requirement. The requirement lacking fulfillment may be related to a process, system, product, or person. In the context of the CAP 15189 Program, a nonconformity is either a minor nonconformity or a major nonconformity.

6.10 Root Cause Analysis

Process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a nonconforming event.