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CAP 15189SM Frequently Asked Questions

Background

In the fall of 2008, The College of American Pathologists (CAP) launched a laboratory accreditation program based on the ISO 15189:2007 standard for medical laboratories. ISO 15189:2007 (or simply "ISO 15189") utilizes specific laboratory accreditation criteria, procedures, and processes to determine laboratory technical competence.

Q. What does "ISO" stand for?

A. ISO is a word chosen by the International Organization for Standardization to refer to a set of standards that apply to all users equally. "ISO" is taken from the Greek word "isos," meaning equal, which is found in the English word "isosceles" (triangle).

Q. What is a "standard"?

A. A standard is a guidance document to the state of art in a specific discipline or technical area developed through expert consensus. It can be thought of as a set of best practices that an organization agrees to adopt and live by. Standards set forth requirements that an organization must meet. Standards do not have the force of law except in those countries that incorporate the requirements into national law.

Q. What is the International Organization for Standardization?

A. The International Organization for Standardization is a worldwide federation of national standards bodies from more than 140 countries, one from each country. It is a non-governmental organization established in 1947. The organization's mission is to promote the development of standardization in order to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological, and economic activity. Its work results in international agreements, which are published as international standards.

Q. What is accreditation to ISO 15189?

A. ISO 15189 is an accreditation program that focuses on the continuum of care directly connected with improved patient safety, risk mitigation and operational efficiency. The accreditation process evaluates quality and competence particular to medical laboratories.

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Q. What is a “quality management system”?

A. It is a set of interacting parts, functions and activities designed to insure quality in an organization’s products and services. These parts, functions and activities typically include:

- A well-planned set of processes for providing a good or service
- Continual analysis and improvement of processes
- Identifying and tracking metrics to monitor quality
- Infrastructure (e.g., quality manager, management review committee, internal auditors) and ongoing activities to support quality
- Periodic internal and external audits with subsequent plans for improvement

Q. How is ISO 15189:2007 accreditation different from ISO 9001:2000 certification?

A. ISO 9001 is a certification/registration of a quality management system and is intentionally very generic.

ISO 15189 incorporates the essential elements of ISO 9001 and adds technical competency factors relevant to medical laboratories. Its primary application is to improve the structure and function of medical laboratories. An accreditation (as opposed to a registration) includes both the certification of the QMS and the evaluation of the competency of the laboratory functions.

ISO 9001 Standard	ISO 15189 Standard
Best fits generic client / provider arrangements Commonly used in manufacturing industry and commercial services	Designed specifically for clinical and medical laboratories
Provides confidence about the organization's QMS	Includes QMS elements, but also assesses a laboratory's technical competence and its ability to provide reliable and accurate test data

If a potential CAP 15189SM client already has an ISO 9001 registration, the decision to keep both the 9001 and 15189 is one that each individual laboratory must make based at a minimum on the value added of each standard, customer requirements, industry requirements, and any applicable regulatory requirements.

Q. What is the relationship of ISO 15189 and ISO/IEC 17025?

A. ISO 15189 is the medical laboratory version of ISO/IEC 17025.

Q. Why is CAP launching the accreditation program to ISO 15189?

A. The CAP's program was developed to help reinforce the ISO goals and standards while supporting CAP's mission of advocating excellence in the practice of pathology and laboratory medicine. CAP was also a significant contributor to the development of the ISO 15189 Standard.

Q. Please explain the process of accreditation to ISO 15189.

A. The stages of the process are as follows:

Stage	Who Does It	Activity
Application	Laboratory	Send CAP QMS and technical documentation requested in application Once the application is complete, CAP assigns a lead assessor who guides the laboratory through the subsequent steps to become accredited to ISO 15189
Internal Audit	Laboratory	Perform internal audit of the laboratory quality management system against the 15189 standard
Desk Assessment	CAP	Offsite review (conducted at CAP office) of documents client has submitted. Purpose is for CAP to study the client's QMS and look for major issues in documentation
Gap Assessment	Laboratory & CAP	Detailed onsite assessment of client's QMS and technical competency by CAP assessors to determine and communicate the scope of work needed for accreditation
Pre Assessment	Laboratory & CAP	One day onsite assessment of client's QMS and technical competency by CAP as final preparation for onsite accreditation assessment
Onsite Accreditation Assessment	Laboratory & CAP	Detailed review of QMS and technical competency, including document control system, records management, and interviews with staff Output of the assessment is a report of the level of conformance and recommendation for or against accreditation
Accreditation	CAP	CAP 15189 Committee reviews assessor report, documentation, and corrective action reports. Committee votes on whether to accredit

Q. How does CAP ensure accurate evaluation of both QMS and technical issues in its ISO 15189 assessments?

A. CAP assigns assessors with complimentary backgrounds – typically a lead assessor, who focuses on QMS issues, and a technical assessor with extensive knowledge of the medical laboratory environment, who focuses on technical issues.

Q. What are the technical factors CAP assessors use in evaluating a laboratory in an ISO 15189 assessment?

A. CAP assessors will conduct a thorough evaluation of all factors in a laboratory that affect the production of patient testing results. These include the following:

- Management of technical areas
- Effectiveness of process and interactions/handoffs
- Effectiveness of integration and continual improvement activities in technical areas
- Organization's ability to sustain an integrated standardized quality management systems approach across all areas of patient testing

- Laboratory's ability to insure quality of patient care by influencing areas beyond traditional boundaries of the laboratory
- Integrity of technical processes, both documented and deployed

Q. How is the CAP 15189 program different from the current CAP Laboratory Accreditation Program (LAP)?

A. The ISO 15189 program compliments the LAP program by increased focus on the management system, whereas the LAP inspection focuses on technical procedures.

CAP 15189	CAP LAP
Voluntary in U.S	Based on CLIA (required in US)
Developed through international expert consensus on medical laboratory best practices	Exceeds U.S. federal regulatory requirements
Focus is on process – the overarching QMS, and the organization's ability to sustain an integrated QMS approach across all parts of an organization with which the laboratory interacts	Focus is on procedures – by integrating more stringent general and discipline specific requirements developed by our member experts with an emphasis on technical and procedural aspects in the laboratory
Full time ISO 15189 assessors, with backgrounds in quality management and medical laboratory work	Volunteer peer assessors who currently work in medical laboratories

Q. Does this replace the CAP LAP inspection?

A. No. The programs are distinctly separate; ISO 15189 does not fulfill US federal regulatory requirements. A laboratory that chooses to become accredited to ISO will experience a separate LAP inspection from the ISO assessment.

Q. How does the timing of the CAP 15189 accreditation program assessment cycle differ from the current CAP LAP inspection cycle?

A. The key differences are as follows:

CAP 15189	LAP Inspection
Initial accreditation depends upon <ul style="list-style-type: none"> • client readiness • internal resource capability • level of the laboratory's commitment 	From date of application, laboratory has 12 months to be inspected.
Once laboratory is accredited, the re-accreditation cycle is a three-year cycle: <ul style="list-style-type: none"> • In the first and second years of this program, two surveillance assessments are scheduled. • During the third year, a re-accreditation onsite assessment takes place. 	Once laboratory is accredited, the re-accreditation cycle is a two-year cycle: <ul style="list-style-type: none"> • Laboratory is required to perform self evaluation 12 months after initial accreditation. • Inspectors will ask to see self evaluation during the re-accreditation inspection.

- Q. How will this influence the licensing or accreditation? Will CLIA accept accreditation to ISO in lieu of the usual accrediting as we do now?**
- A.** No. The accreditation to ISO 15189 is in addition to CLIA '88 accreditation and does not replace it.
- Q. Is there a link to Centers for Medicare & Medicaid Services (CMS) for fees?**
- A.** There is no tie to CMS for reimbursement.
- Q. How widespread is ISO 15189? Is this accreditation program widely accepted?**
- A.** Currently ISO 15189 is an internationally recognized standard, with accreditation organizations offering 15189 in 44 countries. In some countries it is the standard by which laboratories are reimbursed. Although it is not currently a standard in the US, CAP believes that it will further support the goals of a laboratory that is working to achieve best practices in quality management systems.
- Q. What types of laboratories are eligible to participate in CAP's 15189 accreditation program?**
- A.** Any laboratory conducting medical testing is eligible to apply for the accreditation program.
- Q. Where can I find more information regarding the program?**
- A.** Please call: 800-323-4040 option1 or go to www.cap.org/cap15189 for additional information.