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## **ISO and the International Organization for Standardization**

### **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).

In English, ISO has the same letters as the organization, but ISO is not an acronym.

### **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 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 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.

## **ISO 15189**

### **Q. What is ISO 15189?**

- A.** It is an international standard, based on ISO/IEC 17025 and ISO 9001, that specifies requirements for competency and quality that are particular to medical laboratories.

ISO 15189 focuses on the continuum of care directly connected with improved patient safety, risk mitigation and operational efficiency.

The International Organization for Standardization has released three versions of the standard. The first two were released in 2003 and 2007. In 2012, the organization released a revised and updated version of the standard, ISO 15189:2012 (Medical laboratories – Requirements for quality and competence). The standard is often referred to without the version, simply as “ISO 15189.”

**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 widespread is ISO 15189? Is this accreditation program widely accepted?**

- A.** Currently ISO 15189 is an internationally recognized standard, with accreditation organizations offering ISO15189 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, the CAP believes that it will further support the goals of a laboratory that is working to achieve best practices in quality management systems.

**Q. How is ISO 15189 accreditation different from ISO 9001:2008 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. The 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 15189 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 (General requirements for the competence of testing and calibration laboratories).

## **The CAP 15189<sup>SM</sup> Program**

**Q. What is CAP 15189<sup>SM</sup>? What does the “SM” superscript mean?**

**A.** It is a CAP quality management program that provides accreditation to ISO 15189.

<b>ISO 15189</b>	<b>CAP 15189</b>
An international standard, based on ISO/IEC 17025 and ISO 9001, that specifies requirements for competency and quality that are particular to medical laboratories.	A CAP quality management program that offers accreditation to ISO 15189.

The “SM” superscript stands for “service mark,” A service mark is a trademark to identify a service rather than a product.

**Q. How long has the CAP been accrediting to ISO 15189?**

**A.** Since the fall of 2008. At that time, the CAP launched the program based on the ISO 15189:2007 standard.

**Q. Why has CAP launched 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. The CAP was also a significant contributor to the development of the ISO 15189 standard.

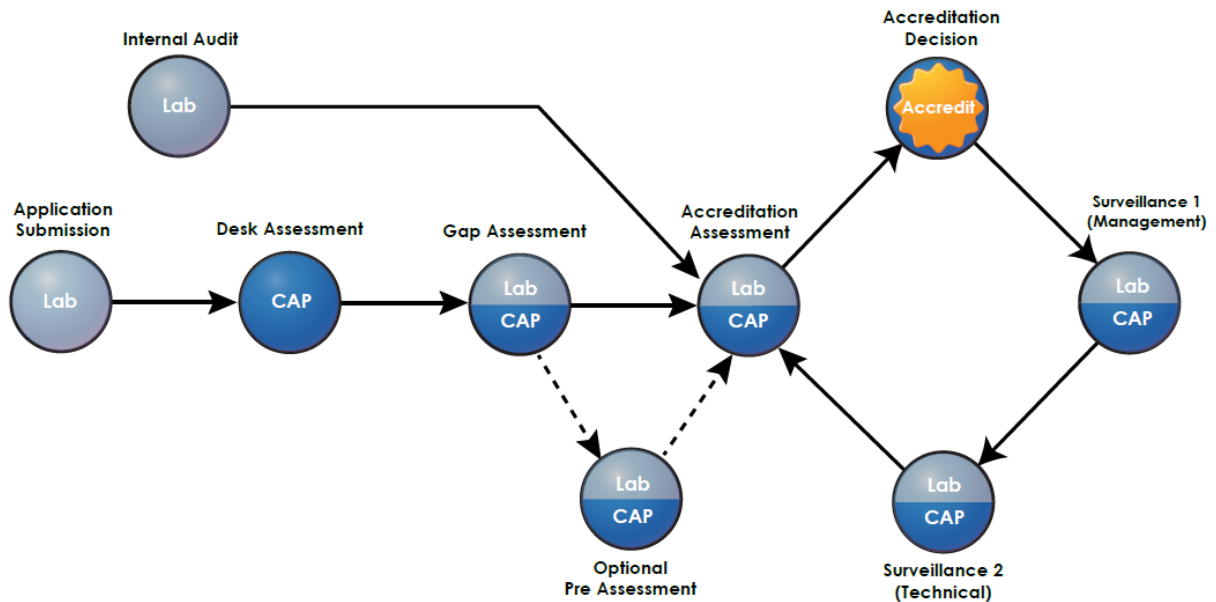
**Q. What are the stages in the CAP 15189 process of accreditation to ISO 15189?**

**A.** The stages of the process are as follows:

Stage	Who Does It	Activity
Application	Laboratory	The laboratory fills out the application form, and sends it to the CAP, along with the requested documentation. <b>Note:</b> Once the application is complete, the CAP assigns a lead assessor, who guides the laboratory through the subsequent steps to become accredited to ISO 15189.
Desk Assessment	CAP	The CAP conducts an offsite review of documents the laboratory has submitted.  The purpose is to study the QMS, look for major issues in the documentation, and evaluate the laboratory's readiness for the accreditation assessment.
Gap Assessment	Laboratory & CAP	The CAP performs a detailed on-site assessment of the QMS and technical competency.  This helps the laboratory scope the work required for accreditation and allows time for corrective actions before the accreditation assessment.
Optional Pre Assessment	Laboratory & CAP	The CAP performs a one-day review of progress after the gap assessment to assess the laboratory's readiness for the accreditation assessment.
Internal Audit	Laboratory	The laboratory performs an internal audit of its QMS against the 15189 standard.  This must be done before the on-site accreditation assessment.
On-site Accreditation Assessment	Laboratory & CAP	The CAP performs a detailed review of the laboratory's QMS and technical competency, including document control system, records management, and interviews with staff.  The output of the assessment is a report of the level of conformance. Subsequently, the assessors make a recommendation to the accreditation committee.
Accreditation	CAP	The CAP 15189 Accreditation Committee reviews the assessor report, documentation, and corrective action reports. The committee votes on whether to accredit.
Surveillance 1 (Management)	Laboratory & CAP	The CAP performs a review of the laboratory's QMS from the standpoint of ISO 15189 Section 4, Management Requirements.
Surveillance 2 (Technical)	Laboratory & CAP	The CAP performs a review of the laboratory's QMS from the standpoint of ISO 15189 Section 5, Technical Requirements.

The diagram below shows the steps in the CAP 15189 process of accreditation in graphic form:

## CAP 15189 Process



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

**CAP 15189 and the CAP Laboratory Accreditation Program**

**Q. How is the CAP 15189 program different from the current CAP Laboratory Accreditation Program?**

- A.** The CAP 15189 program compliments the Laboratory Accreditation Program by increased focus on the management system, whereas the Laboratory Accreditation Program inspection focuses on technical procedures.

Part of the difference is based on the ISO 15189 standard:

ISO 15189 Standard	CAP Laboratory Accreditation Program
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

The CAP 15189 program also differs from the CAP Laboratory Accreditation Program in terms of the accreditation staffing:

CAP 15189	CAP Laboratory Accreditation Program
Full time CAP 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 Laboratory Accreditation Program inspection?**

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

**Q. How does the timing of the CAP 15189 program assessment cycle differ from the current CAP Laboratory Accreditation Program inspection cycle?**

**A.** The key differences are as follows:

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

**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. What types of laboratories are eligible to participate in the CAP 15189 program?**

**A.** Any laboratory conducting medical testing is eligible to apply for the accreditation program.



## ILAC and ISO 15189

### **Q. What is ILAC and what does “ILAC” stand for? What authority does it have?**

- A.** ILAC, or the International Laboratory Accreditation Cooperation, is an association of laboratory accreditors in the field of product testing, calibration, and metrology. It was formed to fill an industry gap, because there was no independent recognition body for product laboratory accreditors. Its focus is on technical, calibration and industrial laboratories under ISO 17025 for product testing.

No government requires ILAC recognition for medical laboratory accreditors, so ILAC recognition is voluntary. ISO does not approve ILAC or any other organization. ISO only produces and oversees standards.

In order to become “recognized” by ILAC, an organization must undergo a peer inspection by another ILAC-recognized accreditor.

There are ILAC-recognized organizations that accredit laboratories to ISO 15189, but this does not make the accreditation any better than one from a non-ILAC accreditor.

ILAC-recognition indicates that an accreditor has been peer reviewed by other ILAC-recognized assessors who specialize in product testing, but do not necessarily have medical laboratory experience.

A peer review by another organization with a product testing specialty can adequately assess an accreditor’s documents and processes; it does not address the accreditor’s expertise in medical laboratory accreditation.

### **Q. Does the CAP plan to become “recognized” by ILAC?**

- A.** We have no such plans. This is a business decision we have made in the interest of our customers. The process of gaining and maintaining ILAC recognition would increase costs for our customers without providing significant benefit.

### **Q. What is the relationship between ISO 17025 (product testing) accreditation competence and ISO 15189 (medical laboratory) accreditation competence? Does one imply the other?**

- A.** Many in the medical community assume that ISO standards are interchangeable for accreditors. They are not.

Accreditation bodies that specialize in product testing are not equally competent to accredit medical laboratories.

The fields of laboratory medicine and metrology have significant differences. There is a vast difference between the testing of live, dynamic human tissue and static objects. Applying the assumptions of metrology and product testing to medical laboratories can result in non-value-added work.

**Q. Does the CAP 15189 program include a pathologist on the accreditation team?**

- A.** CAP 15189 assessment teams do not include an individual pathologist, but because CAP 15189 builds on the CAP Laboratory Accreditation Program (which is a pre-requisite to apply for the CAP 15189 program) laboratories always have a pathologist involved in the assessment of their operations.

The CAP Laboratory Accreditation Program delineates specific points where the pathologist must be involved.

Furthermore, pathologists on the CAP 15189 Committee review the findings of the CAP 15189 assessors and make the final accreditation decision. No other ISO 15189 accreditation program does this. The CAP 15189 committee includes pathologists who shaped the 15189 standard and as TC-212 members have continual oversight of its interpretation and correct application.

To summarize, pathologists are truly involved all the way through the CAP 15189 accreditation process.

**Q. How should medical laboratories go about choosing an ISO 15189 accreditor?**

- A.** Medical laboratories should choose based on the recognized expertise of the accreditor in the relevant disciplines. The CAP is the largest and most experienced accreditor in the world in the specialty of medical laboratory accreditation, leading and enhancing laboratory accreditation for more than 50 years.

Pathologists from CAP have been instrumental in crafting the ISO 15189 standard. The CAP understands the intent of the requirements and how the pieces of the standard fit together. We understand the efforts that are involved in implementing a quality system that meets the standard and improves patient care.

A panel of pathologists and medical laboratory experts oversee the CAP 15189 to ensure the program arrives at sound decisions and policies that will serve the laboratory community and align with ISO 15189.

Laboratories should also choose an accreditor with a sophisticated understanding of quality management systems. A good assessor can help you focus your accreditation efforts on making your laboratory processes more effective, and avoid work that only has relevance to the assessment process, and then sits on the shelf.

**More Information**

**Q. Where can I find more information regarding the CAP 15189 program?**

- A.** Please call: 800-323-4040 option1 or go to [www.cap.org/cap15189](http://www.cap.org/cap15189) for additional information.