JUNE **2025**

IAS AccreditCom®

Medical Laboratories Accreditation Program
N E W S L E T T E R

Welcome to the IAS newsletter for the Medical Laboratory Accreditation Program

This publication is designed to keep IAS customers and industry professionals informed about important developments at IAS and within the medical laboratory accreditation field that may have an impact on your organization and its accreditation.

Introduction to **Medical Laboratory Accreditation**

The IAS Medical Laboratory Accreditation Program provides assurance that laboratories are competent to perform the tests included in their scope of accreditation. Accreditation is based on the ISO 15189:2022 standard, Medical laboratories—Requirements for quality and competence. Many regulators and economies require or strongly encourage medical laboratories to be accredited to ISO 15189, especially those involved in national health programs, public health reporting, or private healthcare services.

The IAS Medical Laboratory Accreditation Program is recognized globally, as IAS is a signatory to the Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation (ILAC).

Laboratories interested in receiving a complimentary quote to apply for accreditation may click on the button below.

REQUEST A QUOTE ▶

IAS Celebrates **50th Anniversary**

IAS is thrilled to celebrate its 50th anniversary of providing accreditation services in 2025! Our journey began in 1975, when we recognized the first testing laboratory under our former name, the International Conference of Building Officials. This laboratory was approved for testing building materials, marking the start of our commitment to excellence.

Over the years, IAS has grown significantly, now offering more than 20 accreditation programs. We proudly serve diverse industries, including food, construction, environmental sciences, information technology and more.

Headquartered in the city of Brea, California, IAS has become a global leader, accrediting organizations worldwide. Our programs are recognized by major regulatory agencies such as the NYC DOB, EPA, FDA, DoD, and many others, underscoring our dedication to quality and trust.

Join us as we celebrate five decades of advancing accreditation and supporting industries worldwide!

IAS moves into a **New Office**

IAS staff have moved into a new office in Brea, California—located within the same building that previously housed the IAS headquarters.

"This new office space has given us the opportunity to expand our office to accommodate growth," said Raj Nathan, IAS President. "It also enabled us to update the environment to reflect the IAS brand and modernize the space with better IT and furnishings to support productivity."

IAS's new address is:

**3060 Saturn Street, Suite 101
Brea, California 92821**

Frequent **Assessment Findings**

Accreditation assessments of medical laboratories have revealed recurring findings related to the implementation of requirements concerning risks to impartiality and risks associated with laboratory activities. These findings are linked to the new revision of ISO 15189:2022, which replaces both ISO 15189:2012 and ISO 22870:2016 (*Point-of-Care Testing – Requirements for Quality and Competence*).

The 2022 edition places greater emphasis on "risk" and the application of risk management across all aspects of laboratory operations, aiming to systematically identify and address risks to patient care as well as opportunities for improvement. The International Laboratory Accreditation Cooperation (ILAC) has announced a three-year transition period, ending on December 31, 2025. ISO 15189:2022 has been aligned with ISO/IEC 17025:2017 and complies with the ISO CASCO common structure for the ISO 17000 series of standards.

In response, many laboratories have developed new procedures for analyzing risks and opportunities or revised existing risk and opportunity documents as part of their corrective actions.
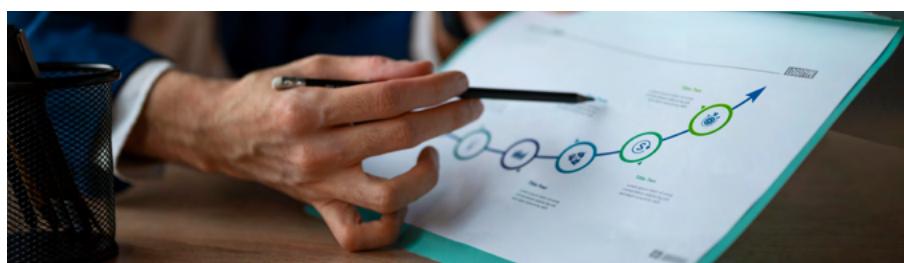
Although laboratories may focus on complying with ISO 15189:2022, many fail to adequately address the broader need to educate staff on risk and risk management principles and how risks and opportunities in relation to pre-examination, examination and post-examination processes of a medical laboratory are identified and mitigated. This gap continues to contribute to recurring nonconformities related to risks to impartiality and risks associated with laboratory activities.

Root cause analyses often identify a lack of awareness of the ISO 15189:2022 requirements as the underlying issue. While some laboratories have responded by providing awareness training on this new standard to relevant staff, the effectiveness of these actions is typically verified during subsequent assessments. Nonetheless, similar nonconformities were often found to persist, indicating that those corrective actions and root cause analyses may not be sufficiently robust.

To address this issue effectively, medical laboratories should complement training on ISO 15189:2022 with awareness of related guidance standards on risk management. For example:

• **ISO 22367** provides detailed guidance on managing risks specific to medical laboratories.

• **ISO 35001** offers a framework for laboratory bio-risk management.

• **ISO 31000** outlines general principles and guidelines for risk management across all sectors.

Finally, the incorporation of new requirements into laboratory quality systems was found to be incomplete in some cases, leading to findings related to failure to implement these updated requirements. In some instances, lack of understanding of the new standard's requirements was identified as the root cause. These findings were subsequently closed after proper training on the new standard was provided. However, many of these findings could have been prevented if laboratories had actively participated in awareness sessions conducted by IAS during the introduction of transition policies and new requirements for medical laboratories.

Extending Your Scope of Accreditation?

Laboratories often extend the scope of the tests and methods in their accreditation to service to a broader range of customers who come to them for work. If you choose to extend your scope, it is important to inform IAS before the assessors arrive at your laboratory to do the regular assessment. IAS assessors plan out their work schedule ahead of time, based on the number of methods in your scope. If you plan to extend your scope, they may need to spend additional time in your laboratory. This extension of scope might be easily accommodated if you let IAS know in advance of the assessment. It can also save on additional costs making the assessment time more efficient.

How Are **IAS Accreditation Criteria Updated**?

If your organization is accredited under the Medical Laboratory Accreditation Program, you are likely familiar with the IAS Accreditation Criteria (AC780) for this program.

To update these criteria, IAS follows a structured process that allows for revisions to be made periodically as needed. Any interested party may propose changes at any time by submitting written revisions to IAS establishing the reasons for the proposed changes. Proposed revisions are reviewed before the IAS Accreditation Committee in a public forum that includes an open discussion session. After this review, the committee may accept, reject, or modify the proposed revisions.
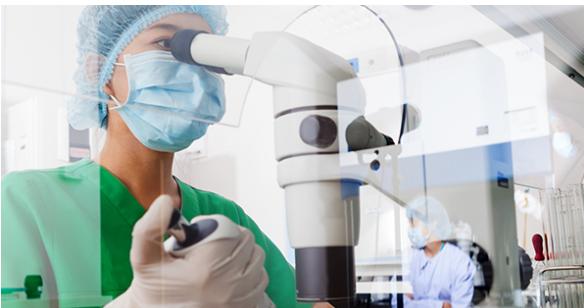
The last IAS Accreditation Committee meeting took place on **June 11, 2025**.

[Learn more about the meeting](#)

Have There Been Updates to AC780 That Affect Your Company's Accreditation?

Be prepared for your next assessment by staying up to date on changes to AC780. Staying informed about these changes helps your company prepare in advance and begin implementing any new requirements.

You can view the most current versions of the accreditation criteria on the IAS website. Updates are indicated with a vertical line in the margin of the affected sections in the document.

Access the latest version of [AC780 here] .

Free Webinar Series for the Medical Laboratory Accreditation Program

IAS has developed an eight-module webinar series about ISO 15189, the standard used to accredit medical laboratories. This on-demand series is free and available to listen and view at your convenience

Topics include:

- **Module 1**: ISO 15189 – Resource and Infrastructure Requirements for Competence in a Medical/Clinical Laboratory
- **Module 2**: ISO 15189 – Method and Process Requirements
- **Module 3**: ISO 15189 – Process Management – Outcomes – Technical Requirements
- **Module 4**: ISO 15189 – System Management Policies – What Is Required?
- **Module 5**: ISO 15189 – Requirements and Procedures for Records
- **Module 6**: ISO 15189 – QA and QC in the Clinical Lab
- **Module 7**: ISO 15189 – Auditing Clinical Lab Processes
- **Module 8**: ISO 15189 – Measurement Traceability of All Laboratory Measurements

View the complete training schedule and course descriptions.

White Paper: Medical Laboratory Accreditation—Purpose and Challenges in ISO 15189 Accreditation

Written by LHD Bandusoma and Dimitrios Katsieris of IAS, this white paper explores medical laboratory accreditation, ISO 15189 requirements, accreditation benefits, challenges, and more

Read the white paper.

Need to Update Your Contact with IAS?

Most accredited organizations will eventually need to update the contact person(s) listed in the IAS Portal. Each accredited customer has three designated contacts who receive communication from IAS: a **Technical Contact**, a **Billing Contact**, and a **Legal Contact**. Although some customers use the same person for all three designations, it is best to assign a different individual to each role.

Each contact has their own login credentials. To update this information, customers must log in to the IAS Portal and make the change directly. It is important to keep these details current—and to ensure more than one individual in your organization has access to the login information.

IAS has created a short video demonstrating how to update contact information.

Watch the instructional video.

International Journal of Conformity Assessment—**Artificial Intelligence**

The upcoming issue of the *International Journal of Conformity Assessment* (IJCA) will focus on Artificial Intelligence. Published by IAS, IJCA provides a high-quality medium for the dissemination of knowledge and methods associated with global conformity assessment practices and concepts.

IJCA is intended for both academics and practitioners in the conformity assessment field. The topics covered include testing, inspection, certification, and accreditation. The journal addresses a wide range of conformity assessment areas, including testing and calibration laboratories, inspection bodies, product certification bodies, management system certification bodies, and organizations offering certification of persons, among others.

Learn more.

2025 Events

The following events may be of interest to professionals working in medical laboratories:

- ➲ **MedExpo Africa**
  June 21-23, 2025 | Nairobi, Kenya
- ➲ **ADLM 2025 Clinical Lab Expo**
  July 29-31, 2025 | Chicago, IL
- ➲ **Medica**
  November 17-20, 2025 | Düsseldorf, Germany
- ➲ **Global Diagnostic Directors' Conclave II**
  July 18–20 2025 | Le Royal Méridien, Chennai, Tamil Nadu, India

Assessor Positions at IAS

IAS is seeking qualified individuals to serve as assessors for the Medical Laboratory Accreditation Program. Learn more about becoming an assessor.

IAS on Social Media

If you haven't connected with IAS on social media, you may be missing out on the latest accreditation news and updates. IAS shares periodic announcements, industry insights, and program information on dedicated pages across X (formerly Twitter), Facebook, LinkedIn, and YouTube. TTo find us, simply visit any of these platforms and search for International Accreditation Service. Be sure to like, follow, and subscribe.

Promote Your Accreditation

IAS customers can promote their accreditations by using IAS Accreditation Program Symbols. The symbols may be used in advertisements, websites, brochures, exhibit booths, and other promotional materials.

To request accreditation symbols, email requestamark@iasonline.org.

Let Us Know **What You Think**

IAS is committed to continually improving our services and values your feedback—positive or negative. We use your input to enhance the support we provide to customers and stakeholders. Visit the Contact Us page of the IAS website to share your comments.

The International Accreditation Service (IAS) is a nonprofit accreditation body and a signatory member of the Asia Pacific Accreditation Cooperation (APAC), the International Accreditation Forum (IAF), and the International Laboratory Accreditation Cooperation (ILAC). .

Need Answers? Get in Touch with IAS

✉ iasinfo@iasonline.org

🌐 www.iasonline.org

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