



PRESENTS

Ref IAF-AB/CO/ADM/2024-25/505

**4 DAYS ADVANCE TRAINING PROGRAMME
CLASSROOM & DISTANCE LEARNING COURSE
ISO 15189 POINT-OF-CARE TESTING (POCT) ACCREDITATION**

Dear Sir,

As is widely known, IAF-AB is conducting various technical courses inviting interested personnel/technocrats for enhancing & fine-tuning of the skill.

IAF-AB organizing **Four Days Advance Training Programme** Classroom & online Training course for ISO 15189 Point-of-care Testing (POCT) Accreditation series management system.

a) ISO INTRODUCTION

The standards published by ISO undergo changes periodically, to reflect the best-suited practices over the changing times. ISO series of standards

For a business unit to successfully set up an ISO 15189 Point-of-care Testing (POCT) Accreditation management systems or get maximum benefits from an established management system, auditors within the organization have to be trained to assess the system ISO 15189 Point-of-care Testing (POCT) Accreditation requirements. They must also be able to assess their suppliers required management system to support own Quality Initiative.

To increase professionalism, quality auditors also seek formal registration with the IAF-AB (UK & INDIA) one of the prerequisites for such registration requires the quality auditors and practitioners to successfully complete an IAF-AB (UK & INDIA) approved auditor training.

b) OBJECTIVE OF THE COURSE:

The objective of the course is to illustrate the importance of the **Four Days Advance Training Programme** role, skills and competency in bearing the ultimate responsibility for the effective performance of the audit team. A practical and intensive course for training quality professionals to External, Internal and manage third and second party audits of an ISO 15189 Point-of-care Testing (POCT) Accreditation Management System.

Course describes how to plan and perform an audit, report findings, conduct opening and closing meetings and establish follow-up action. You will understand by the end of the course how regular auditing by an audit team directed by a competent internal auditor is the foundation of an effective ISO 15189 Point-of-care Testing (POCT) Accreditation

Management System. On completion of the course, you will have the necessary skills and the experience to Internal Audit and manage your own audits. The learning process will include a series of tutorials, exercises, culminating in both practical and written examination. Delegates will be supplied with a bound set of comprehensive course notes.

c) **COURSE CONTENTS:**

- Introduction to ISO 15189 Point-of-care Testing (POCT) Accreditation Management System
- Vocabulary & understanding definitions
- Introduction to ISO 15189 Point-of-care Testing (POCT) Accreditation - Management System Requirements
- Need for Internal Quality Audits
- Auditing Techniques
- Conducting Internal Quality Audits
- Course Examination with minimum 50% passing marks.

Day 1: Introduction to ISO 15189 and POCT Concepts

Session 1: Overview of ISO 15189

- **Introduction to ISO 15189**
 - Definition and scope of ISO 15189.
 - Importance of accreditation in medical laboratories, specifically for POCT.
- **Key Terminology**
 - Definitions of critical terms related to POCT and laboratory accreditation.

Session 2: Understanding Point-of-Care Testing (POCT)

- **What is POCT?**
 - Definition and examples of POCT applications.
 - Benefits and challenges associated with POCT.
- **Regulatory and Accreditation Landscape**
 - Overview of regulations and standards impacting POCT, including national and international perspectives.

Session 3: Core Principles of ISO 15189

- **Structure of ISO 15189**
 - Breakdown of the standard's structure and its key sections.
- **Quality Management System (QMS) Requirements**
 - Overview of QMS elements and their application in medical laboratories.

Session 4: Stakeholders in POCT

- **Roles and Responsibilities**
 - Identifying key stakeholders involved in POCT, including clinicians, laboratory staff, and patients.
- **Collaboration and Communication**
 - Importance of effective communication among stakeholders for successful POCT implementation.

Group Activity:

- Participants engage in group discussions to identify the current status and challenges of POCT in their respective organizations.

Day 2: Implementing ISO 15189 in POCT

Session 5: Developing a Quality Management System for POCT

- **Designing a QMS for POCT**

- Principles of establishing a robust QMS tailored for POCT.
- **Document Control and Management**
 - Importance of proper documentation and record-keeping for compliance with ISO 15189.

Session 6: Competence and Training of Personnel

- **Personnel Competence Requirements**
 - Understanding the necessary qualifications and training for POCT personnel.
- **Developing a Competence Framework**
 - Strategies for ongoing training and assessment of staff competencies.

Session 7: Pre-analytical, Analytical, and Post-analytical Processes

- **Understanding the Testing Process**
 - Overview of the pre-analytical, analytical, and post-analytical phases specific to POCT.
- **Quality Control and Assurance**
 - Implementing quality control measures to ensure accurate and reliable test results.

Session 8: Equipment and Maintenance

- **Selecting Appropriate POCT Devices**
 - Criteria for choosing suitable POCT devices for various applications.
- **Maintenance and Calibration**
 - Importance of regular maintenance and calibration of POCT devices.

Group Activity:

- Participants work in groups to develop a draft QMS framework for POCT, including documentation strategies.

Day 3: Accreditation Process and Internal Audits

Session 9: Preparing for ISO 15189 Accreditation

- **Accreditation Process Overview**
 - Steps involved in obtaining ISO 15189 accreditation for POCT.
- **Conducting Gap Analysis**
 - Techniques for performing gap analysis to identify areas needing improvement.

Session 10: Internal Audits in POCT

- **Internal Audit Principles**
 - Overview of internal audit processes specific to POCT.
- **Preparing for Audits**
 - Best practices for preparing for internal and external audits.

Session 11: Management Review and Continuous Improvement

- **Conducting Management Reviews**
 - Importance of regular management reviews in maintaining an effective QMS.
- **Continuous Improvement Practices**
 - Strategies for fostering a culture of continuous improvement in POCT.

Session 12: Handling Non-conformities and Complaints

- **Identifying Non-conformities**
 - Techniques for identifying and documenting non-conformities in POCT processes.
- **Managing Complaints**
 - Establishing processes for handling complaints from patients and stakeholders.

Group Activity:

- Participants engage in case studies to analyze real-world examples of successful and unsuccessful POCT accreditation processes.
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Day 4: Case Studies, Future Trends, and Course Review

Session 13: Case Studies in ISO 15189 and POCT

- **Learning from Experience**
 - Examination of successful ISO 15189 implementations in POCT settings.
- **Best Practices for Accreditation**
 - Identifying best practices and lessons learned from case studies.

Session 14: Future Trends in POCT and Accreditation

- **Emerging Technologies and Innovations**
 - Overview of emerging trends and technologies in POCT (e.g., mobile health, telemedicine).
- **Impact of Regulatory Changes**
 - Anticipating future regulatory changes and their impact on POCT practices.

Session 15: Course Review and Key Takeaways

- **Recap of Key Concepts**
 - Summary of major topics covered throughout the training.
 - Participants reflect on their learning and how it applies to their organizations.
- **Planning for Implementation**
 - Developing personal action plans for implementing ISO 15189 standards in POCT within participants' organizations.

Session 16: Certification of Completion

- **Issuing Certificates**
 - Participants receive certificates of completion for the training program.
 - **Networking Opportunities**
 - Facilitating networking among participants for future collaboration and support.
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Learning Outcomes:

By the end of this training, participants will:

- Understand ISO 15189 standards and their application in point-of-care testing.
- Develop and implement effective quality management systems for POCT.
- Conduct internal audits and prepare for accreditation assessments.
- Manage non-conformities and complaints effectively.
- Identify emerging trends and future challenges in the field of POCT.

Delivery Method:

- **Classroom Training:** Interactive lectures, group discussions, case studies, and hands-on activities.
- **Distance Learning:** Virtual presentations, downloadable resources, quizzes, and online discussions.

Materials Provided:

- Comprehensive course manual covering ISO 15189 requirements, quality management principles, and best practices in POCT.
- Templates for audit checklists, quality management documentation, and complaint management processes.
- Certificate of completion for participants.

This training program aims to equip participants with advanced knowledge and practical skills necessary for effectively implementing ISO 15189 standards in point-of-care testing

environments, thereby enhancing the quality and reliability of healthcare services provided to patients.

For detail of contents refer our website at <https://iaf-ab.org/>

d) WHO SHOULD ATTEND:

- 1) All employees whose work responsibility directly affects ISO 15189 Point-of-care Testing (POCT) Accreditation.
- 2) Those individuals willing to take up external auditing as a future profession by becoming an independent auditor.
- 3) Those who intend to enroll themselves to IAF-AB (UK & INDIA) Registration Schemes of ISO 15189 Point-of-care Testing (POCT) Accreditation.
- 4) Management Representatives responsible for effective implementation and execution of ISO 15189 Point-of-care Testing (POCT) Accreditation.

e) FACILITIES:

All facility for delegates covering lecture hall, tea and lunch will be arranged by Client or if you are attending the course at IAF-AB office. IAF-AB institute will arrange the above facility.

f) COURSE DETAILS:

Detail program of every days training course will be sent / given on the first day to the delegates on registration.

g) DURATION:

Four days Advance Training program for ISO 15189 Point-of-care Testing (POCT) Accreditation [Timings: 10.00 am to 6.00 pm]

FEES:

- h) 4 Days Advance Training program of ISO 15189 Point-of-care Testing (POCT) Accreditation is Rs 18000+18%GST**

Payment should be made by Cheque / DD in favour of **“IAF-AB, Mumbai”**



Indian Overseas Bank

BANKERS DETILS FOR EFT/ECS/RTGS/NEFT PAYMENT

Sr. No.	Name	Details
1.	Name of Beneficiary	IAF-AB For (UKJAS Accreditation Pvt Ltd)
2.	Name of Bank	Indian Overseas Bank
3.	Bank Branch	Station Road, Palwal Branch, haryana
4.	Bank Branch Code	1667
5.	Account No	166702000000340
6.	RTGS/NEFT / IFSC Code	IOBA 0001667
7.	SWIFT BIC	IOBAINBB089
8.	Account Type	CURRENT
9.	MICR code	110020106
10.	Email Id	info@iaf-ab.org
11.	PAN No.	AVZPS7816G
12.	GST No.	27AVZPS7816G1ZN

We hereby declare that the particulars given above are correct and complete.
Thanking You

Step for Admission:

- 1. Select the course, you want.**
- 2. Choose Classroom/Distance Learning**
- 3. Pay the fees by ECS/RTGS/NEFT to our Indian Overseas Bank Account**
- 4. Send transaction ID/Deposit Slip along with duly filled Registration form**
- 5. Get Confirmation of your admission by email. Admission is based on first cum first serve basis.**
- 6. Currently Classroom training is only available at Mumbai and your office premises/factory, if there are more than 4 participants in the same city/factory . For outside student, Guest house facility is available of Rs 300/per day in Mumbai depends on seat availability; otherwise all ranges of hotels are available near to our institute.**
- 7. Other cities student, who doesn't want to come Mumbai, can opt for Distance Learning Mode. Syllabus is the same. You will be given course material by email and we will recommend some books, which you can buy. Three month time will be allowed to study the course material and for any doubts and faculty interaction can be done one to one on skype is: IAF-AB and whatsapp video call on +91 8275879725 on Sunday between 5.00 to 8 pm. If you want training online we can share presentation on www.googlemeet.com with live presentation. You can attend from any cities around the world.**

i) VENUE:

Client Office

Or

IAF-AB

B-401, New Om Kaveri CHS Ltd, Nagindaspara,

Next to shiv sena office,

Nalasopara (E), Dist. Palghar – 401209, Maharashtra

Email : info@iaf-ab.org

Tel: +91 0250-2341170/+91 9322728183/+91 8369083940

j) NOMINATIONS:

You may send in your nominations to the course co-coordinator, IAF-AB, on the Registration form at the following address along with the fees.

Ranjeet Prasad

+91 8369083940

B-401, New Om Kaveri CHS Ltd, Nagindaspara,

Next to shiv sena office,

Nalasopara (E), Dist. Palghar – 401209, Mumbai, Maharashtra

Email : info@iaf-ab.org

Tel:+91 0250-2341170

Fees once paid will not be refunded, however it could be adjusted against the next course for the same financial year.

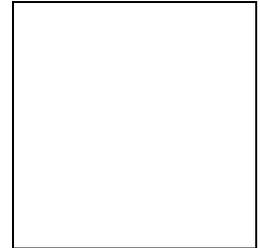
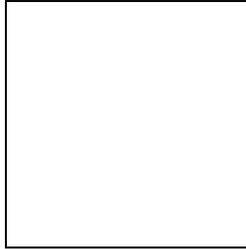
Please send your nomination of the delegated immediately as limited seats are available. Seats are filled on first cum first serve basis.

k) TERMS & CONDITIONS:

- I. IAF-AB general terms and conditions will be applicable for qualification of personnel.
- II. Minimum candidates per batch should be 04 Number and Maximum should be 25 per batch. **10% discount will be offered for** 04 Number and Maximum should be 25 per batch.
- III. Delegate Fees shall be send in advance through cheque / DD in favor of “**IAF-AB**” payable at Mumbai.
- IV. IAF-AB will charge Service tax as applicable.
- V. Travel & Subsistence by 3rd AC train or economy class airfare will be charged for faculties on actual to be borne by client in case of course will be conducted in-house at client premises.



REGISTRATION FORM



PERSONAL DATA

Name in Full :
..... (In Capital Only)

Surname Name Father's/Spouse's Name

Name of the Firm & Address.....
.....

Phone No: (With STD Code) : Sex:

Mobile No: E-mail:

Date of Birth: Qualification:

Training Course:

Place: (Signature)

Date : Name:

PAYMENT MADE BY : Cheque No / Demand Draft No..... Date

Drawn on Bank :

Cheque / Demand Draft Should be drawn in favour of **IAF-AB** payable at Mumbai, Maharashtra, India.

Note : Fees once paid will not be refunded, however this will be carried forward for the next course during the same financial year

IAF-AB, B-401, New Om Kaveri CHS Ltd, Nagindaspara, Next to shiv sena office, Nalasopara (E), Dist. Palghar – 401209, Maharashtra

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UK Head Office:

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