



PRESENTS

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

**5 DAYS LEAD AUDITOR 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 **Five Days Lead Auditor 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 **Five Days Lead Auditor 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 70% passing marks.

Day 1: Introduction to ISO 15189 and Quality Management Systems

- **Session 1: Overview of ISO 15189**
 - Purpose and scope of ISO 15189
 - Importance of accreditation in medical laboratories
 - Differences between ISO 15189 and other ISO standards
- **Session 2: Fundamentals of Quality Management Systems (QMS)**
 - Key principles of QMS
 - Quality policies and objectives
 - Roles and responsibilities in a QMS
- **Session 3: Document Control and Records Management**
 - Importance of documentation
 - Procedures for document control
 - Record-keeping requirements
- **Workshop:**
 - Group activity on developing a quality policy for a POCT laboratory

Day 2: ISO 15189 Requirements for Point-of-Care Testing

- **Session 1: Management Requirements**
 - Organizational structure and governance
 - Management review and improvement processes
 - Resource management, including staff competence and training
- **Session 2: Technical Requirements**
 - Pre-analytical, analytical, and post-analytical phases
 - Quality control and assurance in POCT
 - Equipment calibration and maintenance
- **Session 3: Risk Management and Patient Safety**
 - Identifying and assessing risks in POCT
 - Implementing risk management strategies
 - Patient safety and ethical considerations
- **Workshop:**
 - Case study analysis of POCT implementation and quality challenges

Day 3: Audit Principles and Techniques

- **Session 1: Audit Principles and Types of Audits**
 - Overview of auditing principles
 - Different types of audits: internal, external, and compliance audits

- **Session 2: Planning and Conducting an Audit**
 - Audit planning and preparation
 - Developing audit checklists and plans
 - Communication skills for auditors
- **Session 3: Evidence Collection and Evaluation**
 - Techniques for effective evidence collection
 - Evaluating compliance with ISO 15189 requirements
 - Identifying non-conformities and areas for improvement
- **Workshop:**
 - Role-play exercise on conducting an audit interview

Day 4: Reporting and Follow-Up

- **Session 1: Reporting Audit Findings**
 - Structure of an audit report
 - Best practices for reporting non-conformities
 - Recommendations for corrective actions
- **Session 2: Follow-Up Procedures**
 - Importance of follow-up in the audit process
 - Monitoring corrective actions and improvements
 - Maintaining communication with relevant stakeholders
- **Session 3: Continuous Improvement and Quality Culture**
 - Tools for continuous improvement in POCT
 - Promoting a culture of quality and compliance
 - Leadership's role in sustaining quality
- **Workshop:**
 - Group discussion on strategies for fostering a quality culture in a POCT environment

Day 5: Practical Application and Examination

- **Session 1: Case Studies and Best Practices**
 - Review of successful POCT accreditation case studies
 - Lessons learned and best practices in auditing POCT laboratories
- **Session 2: Mock Audits**
 - Conducting mock audits in small groups
 - Role-playing different audit scenarios
- **Session 3: Examination and Certification**
 - Written examination on course content
 - Feedback session and discussion
 - Certification of completion for participants

Additional Notes:

- **Materials Provided:**
 - Course handbook
 - ISO 15189 standard copies
 - Access to online resources and forums
- **Assessment:**
 - Continuous assessment through participation in workshops and discussions
 - Final examination to evaluate understanding of course content

Target Audience:

- Auditors, laboratory managers, quality assurance personnel, and anyone involved in POCT accreditation processes.

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:

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

FEES:

- h) 5 Days Lead Auditor Training program of ISO 15189 Point-of-care Testing (POCT) Accreditation is Rs 25000+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.

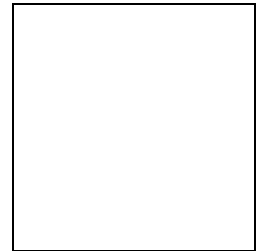
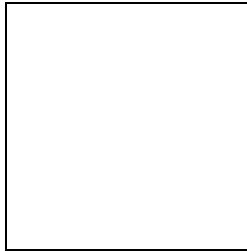
Please send your nomination of the delegated immediately as limited seats are available. Seats are filled on first cum first serve basis.

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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