

# Specific Accreditation Process for Inspection Bodies

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## 1 Purpose

The purpose of this document is to supplement the requirements detailed in EAS P07 by providing additional, inspection programme specific details and / or requirements, for the accreditation of Inspection Bodies (IBs) to ISO/IEC 17020 applicable to regulated and non-regulated(Voluntary) domains.

## 2 Scope

This document outlines inspection programme specific details of how EAS plans and conducts assessments of Inspection Bodies to EAS accreditation requirements, the requirements of the applicable standards / guides, the relevant technical regulation applicable to their field of operation, as well as the International Laboratory Accreditation Co-operation (ILAC) requirements.

**Note 1: Regulatory domain:** Organisations operating currently as Inspection Bodies accredited to ISO/IEC 17020 and the respective regulations and national and international standards applicable in each field:

**Note 2: Voluntary domain:** Organisations operating currently as Inspection Bodies in any Non-regulatory field accredited to ISO/IEC 17020:

**Note 3: Technical Requirements:** are the stipulated requirements applicable for the Accreditation of Inspection Bodies as per to ISO/IEC 17020.

## 3 References

- EAS PM09.0 Policy Manual
- EAS P 07 - EAS Accreditation Process
- EAS P07/03 - Sampling for Assessment
- ISO/IEC 17020 - General criteria for the operation of various types of bodies performing inspection.
- ILAC-P15:05/2020 - Application of ISO/IEC 17020:2012 for the accreditation of Inspection Bodies

## 4 General

4.1 The function of EAS is to assess and recognize the competence of IBs to competently carry out inspections in specified fields and subsequently to ensure, by monitoring, that the required accreditation standards are maintained.

4.2 The accreditation cycle for the area of Inspection in both the Regulatory and Voluntary areas against ISO/IEC 17020 is 4 years and 6 month.

4.3 Assessment of the competence of an IB is carried out using document reviews, visits to the IB's central administrative office and other locations and on-site assessment of inspections. The purpose of the assessment is to determine whether an IB complies with the requirements of ISO/IEC 17020 and the International Laboratory Accreditation Co-operation (ILAC) requirements and the relevant EAS technical requirements, applicable to their field and type of operation.

4.4 EAS uses Technical Assessors (TAs) and/or Technical Experts (TEs) with the relevant specialist knowledge to assess the competence of the IB to perform the inspections for which accreditation is sought.

4.5 Accreditation for the Inspection Body engaged in the Regulatory and Voluntary inspection domain.

4.6 Information on the application of ISO/IEC 17020 is provided in both ILAC-P15:2020 "Application of ISO/IEC 17020:2012 for the accreditation of Inspection Bodies", available from [www.ilac.org](http://www.ilac.org) and EAS Re07.01 "EAS Technical Requirements for the Accreditation of Inspection Bodies on the application of ISO/IEC 17020".

4.7 Inspection documents, procedures and application forms are available on the EAS website [www.EAS-eth.org](http://www.EAS-eth.org).

4.8 Regulatory requirements are described in the relevant EAS documents. Where required, specific

Technical Requirements for specific areas of regulatory inspection are jointly published by EAS and the relevant Government department.

4.9 In addition to those aspects related to inspection that are already addressed in P07.0 the additional requirements apply to regulatory and voluntary inspection bodies as indicated in the clauses that follows.

## **5 Application and document review**

5.1.1 As part of the application process, the applicant IB is required to indicate its level of independence by specifying whether it is operating as type A, B or C (See ISO/IEC 17020:2012 Annex A, clause A.1, A.2 and A.3. and P15:2020). As part of the review of the application and supporting documentation the EAS appointed team leader will also assess and confirm that the information submitted supports the type of inspection body requested.

## 6 Pre-assessment

### 6.1 Inspection Bodies for regulated Products and services

6.1.1 If regulatory bodies has a requirement for having pre-assessment as pre condition for the operation of regulated inspection matters then, EAS shall enforce IBs for pre-assessment before commencing initial assessment. The Pre-assessment can be carried out at a specified location (generally the central office) of the IB to:

- I. Discuss any findings related to the documentation;
- II. Seek further information on the management system;
- III. Briefly examine the systems which have been established and implemented;
- IV. Discuss any arrangements which have been made to include multiple locations, inspectors working from home, sub-contracted activities etc. Within the management system; and
- V. Agree the proposed scope of accreditation;

6.1.2 The Pre-assessment visit shall not be more than two days. The team leader will supply the IB with at least a recommendation report, completed non-conformance forms , completed assessment matrix, completed checklist relevant to the field of inspection, tentative operational certificate if regulatory requested and schedule of accreditation.

**Note:** IB's technical capabilities or competence shall not be evaluated during pre-assessment.

6.1.3 After all, the findings raised during the Pre-assessment have been effectively cleared; EAS shall issue recommendation certificate to the IB highlighting as applicable the following:

- A pre-assessment was conducted on the documentation and implementation of the documented system at the office and this meets the requirements of ISO/IEC 17020 and the specified regulatory requirements.
- No assessment of technical competence was conducted.
- The letter covers the following scope and personnel aspects.
- Scope: List regulations/codes/acts
- Inspection Body Personnel: Technical Manager, Quality Manager, Design Verification Engineer (if applicable), Inspectors, Management Representative (if applicable).

6.1.4 Once recommendation certificate has been issued by EAS ; the IB must apply for provisional approval to the relevant Government Department/Regulatory authority. The

Government/Regulatory authority approval shall enforce the IB to obtain accreditation within 9 months by EAS .

6.1.5 The IB shall provide EAS with a copy of the approval document they obtain from the Government Department/Regulatory authority, in order for EAS to proceed an initial assessment.

6.1.6 The IB shall have an on-site initial assessment within 6 months. The IB shall be required to demonstrate its technical competence by performing inspection functions as detailed on their scope of application for accreditation. Failure to demonstrate technical competence within the defined period will result in the withdrawal of the EAS recommendation certificate and subsequently the IB's "approved" status with the Government/Regulator. A repeat of the entire application process is then required if the IB decides to continue seeking accreditation.

6.1.7 During the 6-month probation period the IB must keep a detailed record of all technical work performed in the regulatory domain that is relevant to their accreditation application. In the event that the IB fails to demonstrate their technical competence within the defined period, resulting in the withdrawal of the EAS recommendation certificate and subsequently the IB's "approved" status by the Government regulatory authority, all work performed in the regulatory domain within the probation period shall be deemed as un-accredited inspection. The IB shall be responsible to ensure that all work performed in the regulatory domain in the probation period is redone once the IB is accredited, at their cost, to ensure that public protection is not compromised.

### 6.2 Inspection Bodies for Voluntary (non-regulated) products and services

6.2.1 Although not mandatory, a Pre-assessment may be carried out on request from the applicant IB, at a specified location (generally the central office) of the IB to:

- I. Discuss any findings related to the documentation;
- II. Seek further information on the management system;
- III. Briefly examine the systems which have been established and implemented;
- IV. Discuss any arrangements which have been made to include multiple locations, inspectors working from home or abroad, subcontracted activities etc. within the management system; and
- V. Agree the proposed scope of accreditation;

### 6.3 Inspection Bodies using multi-standards

6.3.1 A Pre-assessment is mandatory using multi-standard inspection bodies at a specified location, generally the central office. (e.g.: IB applying for accreditation against ISO/IEC 17020 and ISO/IEC 17025).

**Note:** Each Multi-Standard accreditation application will be processed by EAS on merit, also taking into consideration account the ILAC and IAF MRA'/MLA's in place at the time of application.

## 7 Initial Assessment

### A) For regulated inspection

A.1) since document review was conducted during pre- assessment, the initial assessment shall resume based on the conditional operations provided from the outcome of pre-assessment and other subsidiary documents shall be submitted.

- I. Copy of the Regulatory Approved Certificate (Certificate issued before accreditation as referenced in the under "Letter of Acknowledgement").
- II. A confirmation of the IB's staff that can be permanent, par timer and contracted employees.
- III. For any par timer and contracted Inspectors:
  - A copy of the contract terms and conditions (the Inspection Body may delete all references to salary);
  - Evidence of their training/induction in the Inspection Bodies' Management System; and
  - Evidence of monitoring of inspections done by the contracted Inspector.

### B) For voluntary Inspection

#### I. Application for Accreditation and Documentation

CABs that believe they comply with all the requirements for accreditation (Re07.0) complete the relevant Accreditation Application Form (F07/01A, B, C , D) and return it to the EAS office together with the required documentation as detailed in the application form.

To ensure that the application requirements have been fulfilled, accreditation Director or the accreditation team leader or assigned technical personnel will review the application and associated information and documentation for completeness as per F07/18 and will communicate with the CAB by Acknowledgment Letter. If the submitted documents are not complete the accreditation director /team leader or responsible person will interact with the CAB until they are completed. If there is evidence of fraud or if the CAB provides intentionally false or concealed information at any point, the application or initial assessment shall be rejected or terminated.

## II. Resource Review:

The accreditation Director or accreditation team leader will initiate a resource review for allocation of assessment personnel and the required assessment man-days. He or a technical person assigned by him will perform the review by using EAS 's checklist for a resource review (F07/18).

The application shall be accepted once EAS has checked whether the required competencies of assessors or experts to match the requested scope of accreditation in time are available according to **EAS 's list of registered assessors and experts.**

The Accreditation director or accreditation team leader will select the assessment team leader, technical assessors and technical experts, if required. The names and organisations of the team members shall be communicated to the applicant CAB to ensure competence, impartiality and no conflict of interest among the CAB and the team members. The CAB shall confirm in writing to EAS the acceptance of the team members, eventually observers or trainees. If the CAB objects to one or more team members it shall inform the accreditation team leader or responsible person in writing together with a justification. If the accreditation team leader or responsible person accepts the reason for rejection, other personnel will be nominated. If the assessment is accepted or cannot be conducted timely because of unforeseen reasons it shall be communicated to the CAB and a new fitting date will be agreed.

The CAB signs an accreditation agreement with EAS which stipulates legally binding rights and obligations of each party by using form F04/02

**Note:** Assessor/ technical expert shall not be assigned to the team if related or coming from an organisation from which he/she has resigned and /or has been involved in any activities that may lead to conflict of interest until two years have passed.

## III. Review of Documented Information

The accreditation Director or accreditation team leader or shall assign the selected assessment team leader and/or technical assessors, when required, to review the CAB's documentation to assess the level of compliance to the relevant accreditation requirement. Team Leader covers the whole system part and Technical assessors review technical part of the requirement using Forms (F07/06 A, B, C, D, E, F, G). Technical Assessor send the completed checklist to Team leader, and then The Team leader compile document review report . The summary of the review will be reported (refer *Document Review Report* F07/15 A, B, C, D, E, F) to the CAB. It will also be indicated whether the CAB can undergo an on-site assessment, a pre-assessment is recommended or that it needs to address non-conformities before further processing.



Note: The assessment team leader may recommend in justified cases that the on-site assessment can start though not all non-conformities found have been closed. This recommendation is to be approved by the accreditation director/team leader or responsible person and to be reported by him in writing to the CAB.

**After document review accomplished, accreditation Cycle program (F07/03A to F) shall develop to be followed during onsite assessment**

### **7.1 The following process requirements are applicable for Mandatory and Voluntary inspection service**

#### **7.1.1 Quotation:**

The finance directorate shall affirm the accreditation director/ team leader or responsible person that the CAB has paid before assessment is conducted (F07/26) However, because of government purchasing procedure, governmental CABs can pay accreditation service fee once they receive the accreditation service. Based on this information, the financial directorate shall issue a quotation for each step of the accreditation process, based on the accreditation fee structure Reg No. 276/2020. Acceptance of the quotation has to be send to EAS by an authorised person of the CAB.

The accreditation director or team leader or responsible person will calculate the man-days based on the number of methods to be assessed, the nature of working methods, number of persons to be witnessed, number of testing or inspection parameters, complexity of the organization, number of branches and other visible conditions, he/she request for the payment to assessors/experts to the finance directorate (F07/16).

7.1.2 The time required for the initial assessment is normally 2 days, but the actual time required is at the discretion of EAS depending on factors including the complexity of the organisation, the number of applicant technical signatories, the geographical spread of its activities, the structure of the supporting management system, and where relevant, the combination of multi-standards requested as part of the application for accreditation.

7.1.3 The nature of the initial assessment will depend on the scope of accreditation required by the IB and the complexity of the supporting management system that is being operated, however, the



following elements will be covered with due consideration of the issues that have an influence on the outcome of the inspection:

- i) Assessment of the central office;
- ii) Assessment of multiple locations (however named and where applicable);
- iii) Assessment of on-site inspections for different fields and types of inspection and inspectors.

7.1.4 Refer to EAS P07.03 “Sampling for Assessment”, which defines EAS procedure and specific requirements for sampling of sites/premises where key activities are performed, personnel and the scope of accreditation within the accreditation cycle.

**Note 1:** Key activities include policy formulation, process and/or procedure development, process of initial selection of inspectors and, as appropriate, contract review, planning conformity assessments, review and approval of conformity assessments.

**Note 2:** When considering whether a premise is one where key activities are carried out, issues which have an influence on the outcome of inspection will be considered, such as:

- Contract review separate from head office;
- Maintenance of records not kept at head office;
- Maintenance of management system documentation not kept at head office;
- Maintenance and calibration of specific equipment kept separate from head office.

## 7.2 Initial On-Site Assessment

7.2.1 In addition to the initial on-site assessment activities described in P07, section 9, EAS assessment teams for IBs will in addition seek to establish through objective evidence and by using various techniques that the management system supports competence against their schedule of accreditation and that it is appropriate to the IB’s needs, organisational arrangements and methods of operation, including multiple location operations and number of staff members.

7.2.2 The initial assessment is performed to establish full confidence in the competence of the IB. An initial assessment of the multiple location(s) will also need to confirm that the implementation of the management system within the IB, the knowledge of the IB staff of the management system and the interface / communication between the different locations and central office is fit for purpose and operational. Implementation within the multiple locations of these aspects will therefore be assessed.

7.2.3 The following techniques will also be employed to establish that the various procedures are being correctly and fully implemented:

- I. Questioning of management and staff who have an involvement in or bearing on the quality of inspection work;

- II. Examination of records;
- III. Examination of the suitability, maintenance, calibration, control and use of all equipment used for inspection work; and
- IV. Examination of the arrangements for exercising control over sub-contractors and suppliers.

7.2.4 All fields and types of inspections will be subject to an office assessment and technical review. The team will assess the technical competence of inspectors in each field or type of inspection covered by the schedule. This will be done through:

- I. Assessment of the performance of the staff whilst conducting scheduled inspections. The performance of staff is assessed in the central office and where applicable, at other locations where inspections may be performed;
- II. Since the majority of inspections are conducted on-site, a suitable location needs to be visited and the inspections performed there will be assessed and reported on; and
- III. Assessment of inspection reports issued by the IB.

7.2.5 The role of EAS 's representative from permanent staff that accompanies the assessment team, its role is to act as an observer and to ensure whether EAS assessment requirements are followed without any omission by the team without engaging himself in the accreditation assessment process. For regulated inspection, regulatory body has right to observe the assessment process without engaging the accreditation assessment process.

7.2.6 When assessors are witnessing the competency of inspectors they shouldn't disturb the inspection activity rather follow and observe their inspection activities that enables to judge the competency of inspectors. The team will be looking to a minimum the following:-

- I. The inspector(s) has the competence for the inspection performed;
- II. The inspector's competence is consistent with the records;
- III. The inspector has been supplied with all necessary documented inspection methods and procedures;
- IV. The procedures are up-to-date;
- V. The inspector implements the procedures in full and correctly, i.e. no short cuts, or personalised application where it is not permissible to do so;
- VI. Records of all observations are made while on-site as required by the procedure;
- VII. Records clearly identify what has been inspected, the method/procedure used, and when it was inspected;
- VIII. All records and raw data are signed/initialled, stamped and traceable as applicable;

- IX. All findings that indicate immediate or urgent action are reported as required to the customer whilst on site;
- X. Inspection reports/ certificates comply with the IB's, EAS 's, and relevant regulatory and/or standard requirements; and
- XI. Facilities and equipment are fit for the inspection purpose.
- XII. Measuring units are traceable to the primary measuring unit through calibration

7.2.7 If no inspectors cover the entire scope of a specific field, then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt on the competence of inspection staff, the sample size of inspectors assessed on-site may be increased.

7.2.8 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an inspector operates from home, this examination will be arranged at a mutually acceptable location.

7.2.9 As a minimum, one inspector carrying out inspections will be assessed on-site for the fields and types of inspection on the accreditation schedule.

## 8 Six Month Follow-up Assessments

8.1 A follow-up visit to the central office will be conducted approximately 6 months, but not exceeding 12 months after accreditation has been granted. On recommendation by the appointed team leader and after approval by EAS , a branch / satellite CAB may also be included in the 6-month follow-up visit.

8.2 The 6-month follow-up is normally conducted by a team leader and technical assessor. The purpose of the visit is to follow-up on any non-conformances raised at the initial assessment and to ensure that the management system is implemented and functioning properly.

8.3 Where the non-conformances raised at the initial assessment are of such a nature that warrants an on-site verification, some or all of the technical assessors used during the initial assessment may also be included for the 6-month follow-up visit.

8.4 The six month follow-up assessments will normally be limited to:

- I. Verification of the satisfactory clearance of any non-conformances raised at the initial assessment;
- II. A general overview of the continued implementation of management system by the team leader ;

III. Where relevant, an in-depth assessment of any specific area of the management and/or technical system may be undertaken. This will be decided by the EAS in conjunction with the appointed team leader, and would be prompted by any previous non-conformances that created doubts as to continue competence in either a specific area of inspection, or of the IB as a whole.

8.5 For Follow up and Re-assessments EAS will contact the IB prior to the assessment and inform them of the Signatories/Inspectors required to be present at the assessment.

## 9. Scope of Accreditation

9.1 It is EAS's policy to define the scope of an IB's accreditation as unambiguously as possible. IBs will therefore be asked to specify in detail the field, type and range of inspections for which accreditation is sought and the locations at which these activities are to be carried out (refer P07.0 Annex A). The proposed scope will be agreed as far as possible before an assessment. Following a successful assessment, the scope, including standard specifications, methods and procedures relevant to the inspections concerned will be finalised and specified on the IB EAS Accreditation Schedule.

## 10. Multi-Standard Assessment

10.1 In order to meet the demands of the marketplace, an IB may be required to comply with more than one accreditation standard (e.g. inspection in combination with either testing or certification or both).

10.2 As the cost, time and management of different accreditations for the same CAB can be onerous on EAS and the CAB the following:

- I. Where possible, facilities who wish to be assessed to two (2) or more accreditation standards will be assessed to multiple standards at the same assessment, using one team leader knowledgeable in the standards for which accreditation is sought. The technical experts used shall match the different technical scopes for which such multi-standard accreditation is sought.
- II. Where the scopes applied for falls under different EAS programmes (e.g. Inspection and Testing), the application forms for each of the different programmes must be completed in full and submitted to EAS.

10.3 It is important that the IB ensure that the applicable standards relevant to the application are all fully addressed in their documented system preferably documentation shall accommodate the integrated management system.

## 11. Inspection Bodies Operating at Multi location

11.1 An applicant IB that operates from a central office and also through a number of locations may seek a single accreditation provided that the conditions for monitoring of its Inspectors, as specified in ISO/IEC17020 are fulfilled.

11.2 IBs shall under no circumstances franchise their accreditation activities to other IB's or organisations.

11.3 During the initial assessment locations shall be assessed according to sampling procedure P07/03.

11.4 EAS will seek to establish through objective evidence and by using various techniques that:

- I. All IB locations are operating under the same management system and are included in its internal audit programme and central review process.
- II. Temporary locations must be working to the same requirements and may be subject to assessment as part of the accreditation process to confirm and provide evidence of the operation and effectiveness of the system.
- III. If EAS observes non-compliance's at the central office or at any one of the locations of an IB with multiple locations, the corrective action procedure shall apply to all locations where applicable. In the event that the results of any of the assessments of 'sample locations' reveal that there is a significant weakness or inconsistency in the application of the management system, EAS will review the assessment programme.
- IV. Failure by one location to comply with EAS requirements and the requirements of the applicable standard may lead to removal of that location from the schedule of accreditation. If the cause of non-compliance is the lack of central control then the corporate accreditation will be the subject to review by EAS and may lead to suspension or withdrawal of accreditation from all locations.
- V. EAS must be advised of any changes to location addresses and activities. EAS must be notified of the establishment of any new locations from which the IB proposes to offer an accredited service before these can be included in the scope of accreditation. The need for an assessment of the new location will be reviewed and, if appropriate, the schedule of accreditation will be amended and the location included in the programme of follow up and re-assessment for the IB.

## 12. Regional and International Locations

12.1 IB locations, which are operated outside Ethiopia, will be subject to the same accreditation requirements as those located in Ethiopia.

12.2 Where assessments are to be covered in a language other than English, arrangements must be made by the IB for an independent interpreter to be available if required. EAS will conduct and report assessments in English.

### 13. Technical Signatory Applications

13.1 Following receipt of an application for a new IB technical signatory, EAS will determine whether or not there is a need for unscheduled assessment to take place or if an assessment of the requested technical signatory can occur during the IBs scheduled assessment. Factors which will be taken into consideration include the:

- I. Existing scope of accreditation; and
- II. Competency of the existing technical signatories.

### 14. Inspection Bodies providing Accreditation Services

Accredited IBs shall not provide certification / accreditation services to any standard used as a basis for accrediting CABs (e.g. ISO/IEC 17020), as this behaviour of the accredited IB will place EAS , against its will, in the unacceptable situation of having to provide the same service that an accredited CAB performs.

**Note:** It is accepted that an accredited IB may have to assess subcontractors to confirm that they meet the IBs' requirements, which may include accreditation standards such as e.g. ISO/IEC 17025. Documentation issued to subcontractors as a result of a successful assessment should clearly state that this is only for the purposes of the subcontract and is not a certification or accreditation.

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Revision No.	Date Approved	Revision History
1 1.1	2018-10-16 2021-05-13	<p>This document was revised according to ISO/IEC 17011:2017</p> <p>Reference used ILAC P15:05/2020</p> <p>Added Note 3: Technical Requirements: are the stipulated requirements applicable for the Accreditation of Inspection Bodies as per to ISO/IEC 17020.</p> <p>Change clause 6.1. subtitle from Regulatory Inspection Bodies to Inspection Bodies for regulated Products and services</p> <p>6.1.1 Removed VI Finalise the Ensure expertise required for the assessment team.</p> <p>6.1.2 Added tentative operational certificate if regulatory requested and schedule of accreditation and remove and a draft certificate.</p> <p>Under clause 7 Initial Assessment remove Preparation for Assessment—and replace A. For regulated inspection and Included par timers under item No. I and II</p> <p>Clause 7 B item no. II For Volunteer Inspector cancels “If rejection happened more than two times the accreditation director/team leader has the right to reject the application”.</p> <p>Clause 7 B item no. III After document review accomplished, accreditation Cycle program (F07/03A to F) shall develop to be followed during onsite assessment</p> <p>7.1.1. Because of government purchasing procedure, governmental CABs can pay accreditation service fee once they receive the accreditation service.</p> <p>Added clause 7.2.5 The role of EAS ’s representative from permanent staff that accompanies the assessment team, its role is to act as an observer and to ensure whether EAS assessment requirements are followed without any omission by the team without engaging himself in the accreditation assessment process. For regulated inspection, regulatory body has right to observe the assessment process without engaging</p>



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		the accreditation assessment process. Added XII Measuring units are traceable to the primary measuring unit through calibration under clause 7.2.6
1.2	2022-05-09	The document is revised due to the name Ethiopian National Accreditation Office (ENAO) change to Ethiopian Accreditation Service (EAS) and new logo developed.
1.3	2023-02-07	<ul style="list-style-type: none"> <li>Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager).</li> <li>Former director general was resigned and replaced by Mrs. Meseret Tessema.</li> </ul>