

Technical Requirements for the Accreditation of Inspection Bodies on the Application of ES ISO/IEC 17020

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0 Introduction

This Technical Requirement (TR) document provides guidance on the application by EAS of ES ISO/IEC 17020: *Conformity assessment –Requirements for the operation of various types of bodies performing inspection (2012)* in the accreditation of inspection bodies. Explanations are provided where appropriate to help ensure consistent application of the standard. The structure of this document therefore reflects that of the Standard including titles of clauses and their numbering.

The information contained in this document is a reproduction of the text contained in the ILAC publication

ILAC-P15:05/2020 - Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies. For ease of reference, each application note is identified by the relevant clause number of ISO/IEC 17020 and an appropriate suffix, e.g. 4.1.4a would be the first application note on the requirements of clause 4.1.4 of the standard.

These interpretative guidance notes are intended to neither add to nor subtract from the requirements of ISO/IEC 17020: 2012. They are intended to clarify the requirements to assist Inspection Bodies in practically implementing the Standard and to minimize differences of interpretation. This document should therefore be read in conjunction with the standard ES ISO/IEC 17020: 2012.

The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC17020, or in a few cases requirements for the operation of accreditation bodies in ISO/IEC 17011, are considered to be mandatory.

The term “should” is used throughout this document to indicate those provisions which, although not mandatory, are provided by ILAC as a recognized means of meeting the requirements. The term “may” is used to indicate something which is permitted. The term “can” is used to indicate a possibility or a capability. Inspection bodies whose systems do not follow the “should” guidance in this ILAC document will only be eligible for accreditation if they can demonstrate to EAS that their solutions meet the relevant clause of ISO/IEC 17020 in an equivalent or better way.

In case of dispute concerning application of this document, EAS will adjudicate on unresolved matters.

Individual inspection schemes may specify additional requirements for accreditation. This document does not try to identify what such requirements may be or how they shall be implemented.

1 Purpose

The purpose of this technical requirement document is to provide guidance in the application of the standard ES ISO/IEC 17020 that is applicable to all Inspection Bodies operating in the voluntary area.

2 Scope

Inspection activities may overlap with testing and certification activities where these activities have common characteristics.

If accredited Inspection Body decisions are reliant on analytical test results or the results of any sub-contracted specialist service, these tests or services shall, where possible, be carried out by appropriately accredited organizations and the results must be in the form of an endorsed certificate or report.

3 References

ISO/IEC 17000	Conformity assessment — Vocabulary and general principles
ESISO/IEC 17020	General criteria for the operation of various types of bodies performing inspection
ISO/IEC 17011	Conformity assessment – General requirements for accreditation bodies accrediting Conformity assessment bodies.
ILAC P8	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies.
ILAC P15: 2020	Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.
EAS PM 09.0	EAS Policy Manual
EAS IP07	EAS Inspection Specific Criteria

4 Terms, definitions and Acronyms

4.1. Inspection

- 4.1.1. throughout these interpretative notes the word “product” should be understood to include the words “product”, “process”, and “service” as specified in clauses 3.2, 3.3 and 3.4 respectively in the ISO / IEC 17020: 2012.

4.1.2. In recognition of the wide range of industries represented by Inspection Bodies' alternative terminology could be used for what is inspected.

4.1.3. For professional judgment to be effectively exercised the staff member responsible for the Inspection Body, referred to in Clause 6.1 below, shall personally perform the Inspections or effectively supervise the Inspection Body.

4.1.4. The term "installation" may be defined as "a collection of components assembled to jointly achieve a purpose not achievable by the components separately".

4.2 Acronyms

EAS :	Ethiopian National Accreditation Office
TS:	Technical Signatory
CAB:	Conformity Assessment Bodies
IB:	Inspection Bodies
IAF MD:	IAF Mandatory Documents
SS:	Sample Size
EMS:	Environmental Management system
QMS:	Quality Management System
ILAC:	International Laboratories Accreditation Cooperation
IAF:	International Accreditation Forum.

5. General requirements

5.1. General requirements – Impartiality and independence

ISO/IEC 17020 places the highest importance on preventing the undue influencing of inspection activities. (5.2) requires that commercial, financial and other pressures do not compromise impartiality, and recognises that personal and organisational relationships (5.3) potentially compromise impartiality and may need controls (5.4) to maintain impartiality. Finally, it considers independence and classifies bodies into Independence Types A, B and C to signal the nature of the relationships between inspection body and the items inspected. Annex 2 provides additional guidance.

5.1.1. "On an ongoing basis" means that the inspection body identifies a risk whenever events occur which might have a bearing on the impartiality of the inspection body.

5.1.2. The inspection body should describe any of its relationships or its personnel's that could affect its impartiality, to the extent relevant, using organisational diagrams or other means.

- 5.1.3. Annex 1 gives an example of a possible format for impartiality risk analysis.
- 5.1.4. Threats and inducements aimed at inspectors or other inspection body personnel may represent serious risks to impartiality. Threats and inducements may originate from inside or outside the inspection body and may happen at any time. The inspection body should record perceived and explicit risks to impartiality of inspections. All personnel working on behalf of the inspection body, should be aware of the responsibility to act impartially, be involved accordingly in the inspection body's impartiality measures and have appropriate access to provide records as issues arise. The inspection body's analysis of risks to impartiality should include details of the inspection body's responses to such risks.
- 5.1.5. The inspection body should have a documented statement emphasising its commitment to impartiality in carrying out its inspection activities, managing conflicts of interest and ensuring the objectivity of its inspection activities. Actions emanating from the top management should not contradict this statement.
- 5.1.6. One way for the top management to emphasise its commitment to impartiality is to make relevant statements and policies publicly available.
- 5.1.7. An inspection body may have different types of independence (Type A, B or C) for different inspection activities listed on the scope of accreditation. However, it is not possible for an inspection body to offer different independence types for the same inspection activity.
- 5.1.8. Complying with the Type A independence requirements A.1b and A.1.c is binary (yes or no) meaning that partly complying with Type A independence requirements is not possible. This also means that a risk analysis resulting in control measures to minimize the impartiality risks of a situation where there is no compliance with these Types A requirements is not possible. Hence, only elimination of the situation that is not compliant with these Types A requirements is possible.

5.2. Confidentiality

No interpretation required, as per the requirements of ISO/IEC 17020.

6. Structural Requirements

6.1. Structural Requirements - Administrative Requirements

- 6.1.1. The inspection body should describe its activities by defining the general field and range of inspection (e.g. categories/sub-categories of products, processes, services or installations) and the stage of inspection, (see note to clause 1 of the standard) and, where applicable,

the regulations, standards or specifications containing the requirements against which the inspection will be performed. ILAC G28 gives guidance for the Formulation of Scopes of Accreditation for Inspection Bodies.

- 6.1.2. The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's activities.
- 6.1.3. An assessment of 'adequacy' may be based on evidence of agreement between the parties to the contract and consideration of any relevant statutory requirements or scheme rules. The inspection body should be able to show what factors have been taken into account when determining what constitutes "adequate provision". It is not the role of an accreditation body to approve the provision held by an inspection body.

6.2. Structural Requirements - Organization and Management

- 6.2.1. The size, structure, composition and management of an inspection body, taken together, shall be suitable for the competent performance of the activities within the scope for which the inspection body is accredited.
- 6.2.2. "To maintain the capability to perform the inspection activities" implies that the inspection body shall take steps to keep it appropriately informed about applicable technical, scheme and/or legislative developments concerning its activities.
- 6.2.3. Inspection bodies shall maintain their capability and competence to carry out inspection activities performed infrequently (normally with intervals longer than one year). An inspection body may demonstrate its capability and competence for inspection activities performed infrequently through 'dummy inspections' and/or through inspection activities conducted on similar products.
- 6.2.4. The inspection body shall maintain an up-to-date organisational chart or documents clearly indicating the functions and lines of authority for staff within the inspection body. The position of the technical manager(s) and the member of management referenced in clause 8.2.3 should be clearly shown in the chart or documents.
- 6.2.5. It may be relevant to provide information concerning personnel which carry out work tasks for both the inspection body and for other units and departments in order to take into account the involvement and the influence they may have over the inspection activities.
- 6.2.6. In order to be considered as "available", the person shall be either employed or otherwise contracted.

6.2.7. In order to ensure that the inspection activities are carried out in accordance with ISO/IEC 17020, the technical manager(s) and any deputy(ies) shall have the technical competence necessary to understand all significant issues and technologies involved in the performance of inspection activities.

6.2.8. In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.

6.2.9. a The position categories involved in inspection activities are inspectors and other positions which could have an effect on the management, performance, recording or reporting of inspections.

b The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred in 6.2.9a.

7. Resource requirements

7.1. Resource requirements - Personnel

7.1.1. a Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3. Some aspects of competence requirements may already be defined by regulators and scheme owners or specified by clients. Where this is the case, the inspection body should incorporate/reference these requirements into their overall competence definitions. The inspection body remains responsible for the appropriateness of competence definitions and their compliance with the requirements of ISO/IEC 17020.

b for “personnel involved in inspection activities”, see 6.2.7.

c Competence requirements should include knowledge of the inspection body’s management system and ability to implement administrative as well as technical procedures applicable to the activities performed.

d When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.

7.1.2. All requirements of ISO/IEC 17020 apply equally for both employed and contracted persons.

- 7.1.3. The procedure for formally authorising inspectors should specify that the relevant details are documented, e.g. the authorised inspection activity, the beginning of the authorisation, the identity of the person who performed the authorisation and, where appropriate, the termination date of the authorisation.
- 7.1.4. The “mentored working period” mentioned in item b should include participation in inspections at the locations where these inspections are performed.
- 7.1.5. Identification of training needs for each person should take place at regular intervals. The interval should be selected to ensure fulfilment of clause 6.1.6 item c. The results of the review of training, e.g. plans for further training or a statement that no further training is required, should be documented.
- 7.1.6. a A major aim of the monitoring requirement is to provide the inspection body with a tool to ensure the consistency and reliability of inspection outcomes, including any professional judgments against general criteria. Monitoring may result in the identification of needs for individual training or needs for review of the inspection body’s management system.
- b For “other personnel involved in inspection activities”, see 6.2.7n1.
- 7.1.7. a To be considered sufficient, the evidence that the inspector is continuing to perform competently should be substantiated by a combination of information such as; - satisfactory performance of examinations and determinations, - positive outcome of monitoring (see note to clause 7.1.7), - positive outcome of separate evaluations to confirm the outcome of the inspections (this may be possible and appropriate in the case of e.g. the inspection of construction documentation), - positive outcome of mentoring and training, - absence of legitimate appeals or complaints, and - satisfactory results of witnessing by a competent body, e.g. a certification body for persons.
- b An effective program for the on-site observation of inspectors may contribute to fulfil the requirements in clauses 6.2.2 and 7.1.3. The program should be designed considering;
- the risks and complexities of the inspections,
 - results of previous monitoring activities, and
 - technical, procedural or legislative developments relevant to the inspections.

Note: The frequency of on-site observations depends on the issues listed above, but should be at least once during the accreditation re-assessment cycle, however see application note 6.1.9a. If

the levels of risks or complexities, or the results from previous observations, so indicate, or if technical, procedural or legislative changes have occurred, then a higher frequency should be considered. Depending on the fields, types and ranges of inspection covered by the inspector's authorisations, there may be more than one observation per inspector necessary to adequately cover the whole range of required competencies. Also, more frequent on-site observations may be necessary if there is lack of evidence of continuing satisfactory performance.

c This requirement applies even in the case the inspection body has only one technically competent person.

7.1.8. a Records of authorization shall specify the basis on which authorization was granted (e.g. the on-site observation of inspections).

b Records of authorisation should specify the basis on which authorisation was granted (e.g. the on-site observation of inspections). 6.1.7 n 1 Policies and procedures should assist inspection body personnel in identifying and addressing commercial, financial or other threats or inducements which could affect their impartiality, whether they originate inside or outside the inspection body. Such procedures should address how any conflicts of interests identified by personnel of the inspection body are reported and recorded. Note, however, that while expectations for inspector integrity can be communicated by policies and procedures, the existence of such documents may not signal the presence of integrity and impartiality required by this clause.

7.2. Resource requirements -Facilities and Equipment

7.2.1. If controlled environmental conditions are needed, e.g. for the correct performance of the inspection, the inspection body shall monitor these and record the results. If conditions were outside acceptable limits for the inspection to be performed, the inspection body shall record what action was taken.

7.2.2. Continued suitability may be established by visual inspection, functional checks and/or re-calibration. This requirement is particularly relevant for equipment that has left the direct control of the inspection body.

- 7.2.3. Inspection bodies should document and retain the rationale for decisions on the significance of influence of equipment on the inspection results as these decisions are critical foundations for subsequent decisions on calibration and traceability.
- 7.2.4. In order to enable tracking when items are replaced, the unique identification of an item of equipment may be appropriate even when there is only one item available.
- 7.2.5. When controlled environmental conditions are needed, the equipment used to monitor such conditions should be considered as equipment that significantly influences the result of inspections.
- 7.2.6. The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) shall be recorded.
- 7.2.7. Guidelines on how to determine calibration intervals can be found in ILAC G24.
- 7.2.8. When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.
- 7.2.9. According to ILAC P10 it is possible to perform in-house calibration of equipment used for measurements. It is a requirement for accreditation bodies to have a policy to ensure that such in-house calibration services are performed in accordance with the relevant criteria for metrological traceability in ISO/IEC 17025.
- 7.2.10. The preferred routes for inspection bodies who seek external services for calibration of their equipment are defined in ILAC P10 6.2.9 n1 Where equipment is subjected to in-service checks between regular re-calibrations, the nature of such checks, the frequency and acceptance criteria shall be defined.
- 7.2.11. The information provided in 7.2.6n1, 7.2.7 and 7.2.8 for programs of calibration of equipment is valid also for programs of calibration of reference materials.

7.2.12. When the inspection body engages suppliers to perform activities which do not include the performance of part of the inspection, but which are relevant for the outcome of inspection activities, e.g. order registration, archiving, delivery of auxiliary services during an inspection, the editing of inspection reports or calibration services, such activities are covered by the term “services” used in this clause.

7.2.13. The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.

7.3. Resource requirements- Subcontracting

7.3.1. By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1, if the inspection body does not have the required competence and/or resources. However, the task of assessing and interpreting the results of such activities for the purpose of determining conformity may be included in the scope of accreditation, provided adequate competence for this has been demonstrated.

7.3.2. In note 2 to the definition of “inspection” in clause 3.1 it is indicated that in some cases inspection may be examination only, without a subsequent determination of conformity. In such cases clause 6.3.3 does not apply since there is no determination of conformity.

7.3.3. Accreditation is the preferred means to demonstrate the competence of the subcontractor, but in justified situations (on the basis of qualified evaluation/professional judgement) results from non-accredited bodies could be accepted.

7.3.4. If the evaluation of the competence of the subcontractor is based partly or in full on its accreditation, the inspection body shall ensure that the scope of the subcontractor’s accreditation covers the activities to be sub-contracted.

8. Process requirements-Inspection Methods and Procedures

8.1. If the inspection includes measurements, ILAC G27 provides guidance on how to determine which requirements may be relevant.

8.2. For the development of specific inspection methods and procedures the guidance in ISO/IEC 17007 can be used.

- 8.3. Many inspection methods use the human eye to perform visual inspections. Increasingly new technology (e.g drones, cameras, special glasses, IT, artificial intelligence, etc.) is introduced to be used during inspections. This could be as a (partly) replacement of an existing inspection method (like the human eye) or as a new inspection method.
- 8.4. Aspects that require attention with the introduction of new technology are:
- Validation of the new or changed inspection method using new technology. In case of (partly) replacement of an existing inspection method, it should be investigated whether the inspection outcome is equally (or more) reliable than the outcome of the existing method;
 - The applicable legal and safety requirements (like permits), legal limitations and legal conditions;
 - The applicable limitations and conditions for the inspection method when new technology is used;
 - Whether the use of new technology should be mentioned in the inspection report;
 - Whether the use of new technology should be mentioned on the inspection and/or accreditation scope.
- 8.5. Where appropriate the contract or work order control system should also ensure that; - contract conditions are agreed - personnel competence is adequate - any statutory requirements are identified - safety requirements are identified - the extent of any subcontracting arrangements required is identified For routine or repeat work requests the review may be limited to considerations of time and human resources. An acceptable record in such cases would be an acceptance of the contract signed by an appropriately authorised person.
- 8.6. In situations where verbal work orders are acceptable, the inspection body shall keep a record of all requests and instructions received verbally. Where appropriate, the relevant dates and the identity of the client's representative should be recorded.
- 8.7. The contract or work order control system should ensure that there is a clear and demonstrable understanding between the inspection body and its client of the scope of the inspection work to be undertaken by the inspection body.

8.8. The information referred to in this clause is not information provided by a subcontractor, but information received from other parties, e.g. a regulating authority or the client of the inspection body. The information may include background data for the inspection activity, but not results of the inspection activity. 7.1.7 No interpretation required, as per the requirements of ISO/IEC 17020.

9. Process requirements - Inspection records

The records should indicate which particular item of equipment, having a significant influence on the result of the inspection, has been used for each inspection activity.

10. Process requirements - Inspection reports and inspection certificates

10.1. ILAC P8 provides requirements for the use of accreditation symbols and for claims of Accreditation status.

11. Management system requirements - Options

11.1. The expression “this International Standard” is a reference to ISO/IEC 17020.

11.2. Option B does not require that the inspection body's management is certified to ISO 9001. However, when determining the extent of required assessment, the accreditation body should take into consideration whether the inspection body has been certified against ISO 9001 by a certification body accredited by an accreditation body which is a signatory to the IAF MLA, or to a regional MLA, for the certification of management systems.

12. Management system requirements – Management system documentation (Option A)

12.1. The policies and objectives shall address the competence, impartiality and consistent operation of the inspection body.

12.2. For easy reference, it is recommended that the inspection body indicates where the requirements of ISO/IEC 17020 are addressed, e.g., by means of a cross reference table.

13. Management system requirements – Control of records (Option A)

13.1. This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained.

13.2. In cases where electronic seals or authorizations are used for approvals, access to the electronic media or seal should be secure and controlled.

14. Management system requirements – Management review (Option A)

14.1. A review of the impartiality risk identification process and its conclusions (clauses 4.1.3/4.1.4) should be part of the annual management review.

14.2. The management review should take into account information on the adequacy of current human and equipment resources, projected workloads and the need for training of both new and existing staff.

14.3. The management review should include a review of the effectiveness of systems established to ensure adequate competence of the personnel.

15. Management system requirements – Internal audits (Option A)

15.1. The inspection body should ensure that all requirements of ISO/IEC 17020 are covered by the internal audit program within the accreditation cycle. The requirements to be covered shall be considered for all fields of inspection and for all premises where inspection activities are managed or performed. The inspection body shall justify the choice of audit frequency for different types of requirements, fields of inspection and premises as part of audit planning performed. The justification may be based on considerations such as;

- criticality,
- maturity,
- previous performance,
- organisational changes,
- procedural changes, and
- efficiency of the system for transfer of experience between different operational sites and between different fields of operation.

15.2. The internal audit is an essential tool the inspection body should apply with a frequency short enough to monitor its capacity to consistently fulfil the requirements in ISO/IEC 17020. When an inspection body detects problems that affect the fulfilment of any ISO/IEC

17020 requirement (e.g. a rise in complaints and appeals; unsatisfactory results at external audits; issues with personnel qualification, etc.), it should consider increasing the frequency and depth of its internal audits, and/or to extend their coverage to include other locations and fields of inspection.

15.3. Competent externally contracted personnel may carry out internal audits.

16. Management system requirements – Preventive actions (Option A)

16.1. Preventive actions are taken in a pro-active process of identifying potential nonconformities and opportunities for improvement rather than as a reaction to the identification of non-conformities, problems or complaints.

Annex A Independence requirements for inspection bodies

Ai Annex A.1 and A.2 of ISO/IEC 17020 refer to the phrase “items inspected” with respect to Type A and Type B inspection bodies (4.1.6 n1 clarifies the cases where an inspection body may have different types of independence). In Annex A.1 b it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected”. In Annex A.2 c it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected”. The reference to “they” in the above sentences is a reference to the inspection body concerned and its personnel. The items in this case are those items that are specified in the accreditation body’s certificate/annex with respect to the accredited scope of the inspection body (e.g. pressure vessels).

A ii. It is also considered as a conflicting activity the provision of consultancy in the design, manufacture, supply, installation, purchase, use or maintenance of the items inspected.

A iii. A ‘regulatory requirement’ means that the exception has been written into relevant legislation and/or where a Regulator provides publicly available guidance stating that this exception is permissible when undertaken as part of the regulated inspection activity.

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