



Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

ILAC-P15:07/2016

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1. INTRODUCTION

This document provides information for the application of ISO/IEC 17020:2012 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection* for the accreditation of inspection bodies. It is intended to be used by accreditation bodies assessing inspection bodies for accreditation as well as by inspection bodies seeking to manage their operations in a manner fulfilling the requirements for accreditation.

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.

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 the accreditation body that their solutions meet the relevant clause of ISO/IEC 17020 in an equivalent or better way.

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.

When using ISO/IEC 17020 and this application document the accreditation bodies should neither add to, nor subtract from, the requirements in ISO/IEC 17020. Note, however, that accreditation bodies must still fulfill the requirements of ISO/IEC 17011.

2. AUTHORSHIP

This publication was prepared by the ILAC Inspection Committee (IC) and endorsed for publication following a successful ballot of the ILAC voting membership in 2014.

An amendment to clarify clause 8.1.3 was proposed by the ILAC IC and endorsed by the ILAC membership in July 2016.

3. IMPLEMENTATION

In order to comply with the provisions of IAF/ILAC A2 clause 2.1.1, signatories to the ILAC MRA shall implement this document within 18 months from the date of publication.

Implementation of the amendment to clause 8.1.3, endorsed by the membership in July 2016, is from the date of publication on the ILAC Website.

4. TERMINOLOGY

For the purposes of this document the terms and definitions given in ISO/IEC 17000 and ISO/IEC 17020 apply.

5. APPLICATIONS OF ISO/IEC 17020:2012

Terms and definitions

- 3.1a The term “installation” may be defined as “a collection of components assembled to jointly achieve a purpose not achievable by the components separately”.

General requirements – Impartiality and independence

- 4.1.3a Risks to the impartiality of the inspection body shall be considered whenever events occur which might have a bearing on the impartiality of the inspection body or its personnel.
- 4.1.3b The inspection body should describe any relationships that could affect its impartiality to the extent relevant, using organisational diagrams or other means.

Examples of relationships that could influence the impartiality include:

- Relationship with a parent organisation
 - Relationships with departments within the same organisation
 - Relationships with related companies or organisations
 - Relationships with regulators
 - Relationships with clients
 - Relationships of personnel
 - Relationships with the organisations designing, manufacturing, supplying, installing, purchasing, owning, using or maintaining the items inspected
- 4.1.5a 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.
- 4.1.5b One way for the top management to emphasise its commitment to impartiality is to make relevant statements and policies publicly available.

Structural requirements – Administrative requirements

- 5.1.3a 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.

- 5.1.4a The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's operations.

Structural requirements – Organisation and management

- 5.2.2a 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.
- 5.2.2b “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 and/or legislative developments concerning its activities.
- 5.2.2c 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.
- 5.2.3a 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.
- 5.2.4a 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.
- 5.2.5a In order to be considered as “available”, the person shall be either employed or otherwise contracted.
- 5.2.5b 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 involved in the performance of inspection activities.
- 5.2.6a In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.
- 5.2.7a 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.
- 5.2.7b The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred to in 5.2.7a.

Resource requirements – Personnel

- 6.1.1a Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3a.
- 6.1.1b For “personnel involved in inspection activities”, see 5.2.7a.
- 6.1.1c 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.
- 6.1.1d When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.
- 6.1.2a All requirements of ISO/IEC 17020 apply equally for both employed and contracted persons.
- 6.1.5a 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.
- 6.1.6a The “mentored working period” mentioned in item b normally includes activities where inspections are performed.
- 6.1.7a 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.
- 6.1.8a 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.
- 6.1.8b For “other personnel involved in inspection activities”, see 5.2.7a.
- 6.1.9a 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 report reviews, interviews, simulated inspections and other performance assessments (see note to clause 6.1.8),
 - 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.

6.1.9b An effective program for the on-site observation of inspectors may contribute to fulfil the requirements in clauses 5.2.2 and 6.1.3. 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.

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.

6.1.9c In inspection areas where the inspection body has only one technically competent person the internal observation on-site cannot take place. In such cases the inspection body shall have arrangements in place for external observations on-site, unless other sufficient supporting evidence that the inspector is continuing to perform competently is available (see 6.1.9a).

6.1.10a Records of authorisation should specify the basis on which authorisation was granted (e.g. the on-site observation of inspections).

6.1.11a Remuneration methods that provide incentives to perform inspections quickly have the potential to negatively affect the quality and outcome of inspection work.

6.1.12a 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.

Resource requirements – Facilities and equipment

6.2.1a Equipment required to carry out inspection in a safe manner may include e.g. personal protective equipment and scaffolding.

6.2.3a 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. See also clause 8.7.4.

- 6.2.3b 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.
- 6.2.4a 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.
- 6.2.4b 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.
- 6.2.4c When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.
- 6.2.6a The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) should be recorded.
- 6.2.6b Guidelines on how to determine calibration intervals can be found in ILAC G24.
- 6.2.7a 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.
- 6.2.7b According to ILAC P10 the preferred routes for conformity assessment bodies who seek external services for calibration of their equipment are defined in sub-sections 1) and 2) of section 2 in ILAC P10. If however, it is not possible to comply with these two routes for any justifiable reason, then it is acceptable to use the routes 3a) or 3b) of section 2 of ILAC P10. It is a requirement for accreditation bodies to have a policy to ensure that such external calibration services meet the relevant criteria for metrological traceability in ISO/IEC 17025.
- 6.2.7c Where traceability to national or international standards of measurement is not applicable, the participation in relevant comparison programs or proficiency tests is an example of how to obtain evidence of correlation or accuracy of inspection results.
- 6.2.8a When inspection bodies use reference standards of measurement to calibrate working instruments the reference standards of measurement should have a higher degree of accuracy than that required of the working instruments they are used to calibrate.

- 6.2.9a Where equipment is subjected to in-service checks between regular re-calibrations, the nature of such checks, the frequency and acceptance criteria should be defined.
- 6.2.10a The information provided in 6.2.7a, 6.2.7b and 6.2.7c for programs of calibration of equipment is valid also for programs of calibration of reference materials.
- 6.2.11a 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.
- 6.2.11b The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.
- 6.2.13a Factors that should be considered in protecting the integrity and security of data include;
- backup practices and frequencies,
 - effectiveness in restoring data from backup,
 - virus protection, and
 - password protection.

Resource requirements – Subcontracting

- 6.3.1a Inspection activities can overlap with testing and certification activities where these activities have common characteristics (See Introduction of ISO/IEC 17020). For example, examination of a product and testing of the same product can both be the basis for the determination of conformity in an inspection process. It should be noted that ISO/IEC 17020 specifies requirements for bodies performing inspection, whereas the relevant standard to apply for bodies performing testing is ISO/IEC 17025 or ISO 15189.
- 6.3.1b 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.
- 6.3.3a 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.
- 6.3.4a 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.

Process requirements - Inspection methods and procedures

7.1.5a 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.

7.1.5b 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.

7.1.5c 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.

7.1.6a 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.

Process requirements - Inspection records

7.3.1a 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.

Process requirements - Inspection reports and inspection certificates

7.4.2a ILAC P8 requires accreditation bodies to specify rules for the use of accreditation symbols on reports and certificates. It should be noted that for endorsed reports and certificates, that is reports and certificates making reference to accreditation, such rules shall include the requirement that inspection bodies include a clear disclaimer;

- when not accredited for services/tests listed on reports and certificates (see full text in section 8.1), and
- when reports and certificates include or are based on results from unaccredited subcontractors (see full text in section 9.3).

- 7.4.4a It may be useful to identify the inspection method in the inspection report/certificate when this information supports an appropriate interpretation of the inspection results.

Management system requirements – Options

- 8.1.3a The expression “this International Standard” is a reference to ISO/IEC 17020.
- 8.1.3b Option B does not require that the inspection body's management system 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.

Management system requirements – Management system documentation (Option A)

- 8.2.4a 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.

Management system requirements – Control of records (Option A)

- 8.4.1a This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained.
- 8.4.1b In cases where electronic seals or authorizations are used for approvals, access to the electronic media or seal should be secure and controlled.

Management system requirements – Management review (Option A)

- 8.5.1a 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.
- 8.5.1b 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.
- 8.5.1c The management review should include a review of the effectiveness of systems established to ensure adequate competence of the personnel.

Management system requirements – Internal audits (Option A)

- 8.6.4a The inspection body shall ensure that all requirements of ISO 17020 are covered by the internal audit program within the accreditation re-assessment cycle. The requirements to be covered shall be considered for all fields of inspection and for all premises where key activities are performed (see IAF/ILAC A5).

The inspection body shall justify the choice of audit frequency for different types of requirements, fields of inspection and premises where key activities are 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.

8.6.5a Competent externally contracted personnel may carry out internal audits.

Management system requirements – Preventive actions (Option A)

8.8.1a Preventive actions are taken in a pro-active process of identifying potential non-conformities 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

Aa 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. 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).

Ab Under bullet point d) reference is made to linkages to separate legal entities engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected. Such linkages include common owners and common owners’ appointees on boards or equivalent. These linkages are acceptable if persons involved do not have the possibility to influence the outcome of an inspection. In particular there exists a possibility to influence the outcome of an inspection if the person has the ability to;

- influence the selection of inspectors for specific assignments or customers, or
- influence decisions on conformity in specific inspection assignments, or
- influence remuneration for individual inspectors, or
- influence remuneration for specific assignments or customers, or
- initiate the use of alternative work practices for specific assignments.

6. REFERENCES

- 6.1 ISO/IEC 17000 Conformity assessment – Vocabulary and general principles.
- 6.2 ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- 6.3 ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection.
- 6.4 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- 6.5 ISO 15189 Medical laboratories – Requirements for quality and competence
- 6.6 ISO 9001 Quality management systems – Requirements
- 6.7 IAF/ILAC A2 IAF/ILAC Multi-lateral mutual recognition arrangements (Arrangements): Requirements and procedures for evaluation of a single accreditation body
- 6.8 IAF/ILAC A5 IAF/ILAC Multi-lateral mutual recognition arrangements (Arrangements): Application of ISO/IEC 17011:2004
- 6.9 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
- 6.10 ILAC P10 ILAC policy on traceability of measurement results
- 6.11 ILAC G24 Guidelines for the determination of calibration intervals of measuring instruments