



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

ILAC-P15:05/2020

ILAC – International Laboratory Accreditation Cooperation

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of “accredited once, accepted everywhere”.

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Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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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. 4.1.4 n1 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/IEC 17020, 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.

This version of the document includes guidance on emerging technologies that are not addressed in ISO/IEC 17020:2012, and takes in consideration that inspection can be an activity embedded in a larger process including testing and certification.

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.

The examples that were included in the previous version of the document were removed and added to the Inspection Committee FAQ database on the ILAC website: <https://ilac.org/about-ilac/faqs/>

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 2020.

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.

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

- 3.1 n1 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

ISO/IEC 17020 places the highest importance on preventing the undue influencing of inspection activities. (4.1.2) requires that commercial, financial and other pressures do not compromise impartiality, and recognises that personal and organisational relationships (4.1.3) potentially compromise impartiality and may need controls (4.1.4) 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

- 4.1.3 n1 “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.

- 4.1.3 n2 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.

- 4.1.3 n3 Annex 1 gives an example of a possible format for impartiality risk analysis.

- 4.1.4 n1 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.

- 4.1.5 n1 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.

- 4.1.5 n2 One way for the top management to emphasise its commitment to impartiality is to make relevant statements and policies publicly available.

- 4.1.6 n1 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.

- 4.1.6 n2 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 Type A requirements is not possible. Hence, only elimination of the situation that is not compliant with these Type A requirements is possible.

Structural requirements – Administrative requirements

- 5.1.3 n1 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.
- 5.1.4 n1 The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body's activities.
- 5.1.4 n2 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.

Structural requirements – Organisation and management

- 5.2.2 n1 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.
- 5.2.2 n2 "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.
- 5.2.2 n3 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.
- 5.2.3 n1 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.
- 5.2.4 n1 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.

- 5.2.5 n1 In order to be considered as “available”, the person shall be either employed or otherwise contracted.
- 5.2.5 n2 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.
- 5.2.6 n1 In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.
- 5.2.7 n1 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.
- 5.2.7 n2 The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred to in 5.2.7n1.

Resource requirements – Personnel

- 6.1.1 n1 Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3n1. 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.
- 6.1.1 n2 For “personnel involved in inspection activities”, see 5.2.7n1.
- 6.1.1 n3 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.
- 6.1.1 n4 When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.
- 6.1.2 n1 All requirements of ISO/IEC 17020 apply equally for both employed and contracted persons.
- 6.1.5 n1 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.
- 6.1.6 n1 The “mentored working period” mentioned in item b should include participation in inspections at the locations where these inspections are performed.
- 6.1.7 n1 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.

6.1.8 n1 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.

6.1.8 n2 For "other personnel involved in inspection activities", see 5.2.7n1.

6.1.9 n1 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 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.

6.1.9 n2 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 6.1.9n1. 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.

6.1.9 n3 This requirement applies even in the case the inspection body has only one technically competent person.

6.1.10 n1 Records of authorisation should specify the basis on which authorisation was granted (e.g. the on-site observation of inspections).

6.1.12 n1 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

- 6.2.3 n1 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.
- 6.2.3 n2 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.
- 6.2.4 n1 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.
- 6.2.4 n2 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.
- 6.2.4 n3 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.
- 6.2.6 n1 The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) shall be recorded.
- 6.2.6 n2 Guidelines on how to determine calibration intervals can be found in ILAC G24.
- 6.2.6 n3 When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.
- 6.2.7 n1 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.
- 6.2.7 n2 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.
- 6.2.10 n1 The information provided in 6.2.7n1, 6.2.7n2 and 6.2.9.n1 for programs of calibration of equipment is valid also for programs of calibration of reference materials.
- 6.2.11 n1 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.

- 6.2.11 n2 The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.

Resource requirements – Subcontracting

- 6.3.1 n1 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.

- 6.3.3 n1 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.

- 6.3.4 n1 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.

- 6.3.4 n2 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

- 7.1.1 n1 If the inspection includes measurements, ILAC G27 provides guidance on how to determine which requirements may be relevant.

- 7.1.1 n2 For the development of specific inspection methods and procedures the guidance in ISO/IEC 17007 can be used.

- 7.1.1 n3 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.

- 7.1.3 n2 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.

7.1.5 n1 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.

7.1.5 n2 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.

7.1.5 n3 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.

7.1.6 n1 The information referred to in this clause is not information provided by a sub-contractor, 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

7.3.1 n1 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

7.4.2 n1 ILAC P8 provides requirements for the use of accreditation symbols and for claims of Accreditation status.

Management system requirements – Options

8.1.3 n1 The expression “this International Standard” is a reference to ISO/IEC 17020.

- 8.1.3 n2 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.

Management system requirements – Management system documentation (Option A)

- 8.2.1 n1 The policies and objectives shall address the competence, impartiality and consistent operation of the inspection body.
- 8.2.4 n1 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)

- 8.4.1 n1 This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained.
- 8.4.1 n2 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)

- 8.5.2 n1 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.
- 8.5.2 n2 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.
- 8.5.2 n3 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)

- 8.6.4 n1 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.

8.6.4 n2 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.

8.6.5 n1 Competent externally contracted personnel may carry out internal audits.

Management system requirements – Preventive actions (Option A)

8.8.1 n1 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

- A n1 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 n2 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 n3 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.

6. Annex 1: Possible format for an impartiality risk analysis (Informative)

Clause 4.1.3 requires the inspection body to identify risks to impartiality on an ongoing basis and clause 4.1.4 requires the inspection body to demonstrate how it eliminates or minimizes such risks. In practice the combination of these two clauses indicates that “an impartiality risk analysis” is required. Although this term “impartiality risk analysis” is not mentioned in ISO/IEC 17020, in this application note it is used as a widely spread term through which the requirements of clauses 4.1.3 and 4.1.4 may be addressed by the inspection body.

The actions through which the inspection body demonstrates how it eliminates or minimizes the identified impartiality risks in practice are often called “control measures”. Also this term is not mentioned in ISO/IEC 17020.

A possible format for an impartiality risk analysis is shown in the table below.

Situation	Impartiality risk	Control measure and its monitoring	Where in the management system is control measure embedded (procedure, instruction, form, statement)?
1. Activities of the inspection body			
-			
-			
-			
-			
2. Relationships of the inspection body			
-			
-			
-			
-			
3. Relationships of personnel			
-			
-			
-			
-			

Table 1. Possible format for an impartiality risk analysis

7. Annex 2: Relationship between impartiality and Type A independence requirements (Informative)

- Impartiality (defined as presence of objectivity) is the leading requirement;
- Impartiality of an inspector is present when the inspector in all cases demonstrates objectivity in his/ her judgement;

1- Risks Eliminated by complying to Type A independence requirements

- Complying with the Type A independence requirements eliminates the impartiality risks related to engaging in activities that may conflict with the independence of judgment and integrity in relation to inspection activities;
- The Type A independence requirements are meant to increase confidence in impartiality and exclude only certain impartiality risks. Hence, complying with these Type A independence requirements does not eliminate all impartiality risks;
- The remaining impartiality risks have to be identified (4.1.3) and minimized or eliminated (4.1.4);

2- Impartiality Risk Analysis and Control Measures

- In practice, the identification of the potential risks to impartiality is often called “**impartiality risk analysis**”; the minimization or elimination of impartiality risks according to 4.1.4 in practice is often called “**control measures**”;
- An impartiality risk analysis is required for all three types of independence (Type A, Type B and Type C);
- Complying with the Type A independence requirements A.1b and A.1c is binary (yes or no) meaning that partly complying with these 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 Type A requirements is not possible. Hence, **only elimination of the situation that is not compliant with these Type A requirements is possible**;
- The Type A independence requirements A.1d could be addressed through control measures resulting from the risk analysis;
- The assessment whether an inspection body complies with the Type A independence requirements A.1b and A.1c can be complex in some specific situations (depending on the items inspected at hand and market characteristics), but the outcome must be yes or no;

3- Items Inspected

- The term “items inspected” is mentioned in the Type A independence requirements of Annex A.1b/c of ISO/IEC 17020 and is clarified in this document ILAC-P15 under A n1.
- The reasoning behind the ILAC-P15 clarification is that possible influence on the market or possible influence from the market should be prevented, thus also preventing commercial/ financial pressures on the inspection body and/ or its personnel (e.g. inspectors);
- Inspection bodies may operate in markets with different characteristics in terms of the number of suppliers/ producers:
 - Markets where there is a limited number of suppliers/ producers. For instance, elevators, cars, pressure equipment;
 - Markets where there is a very large number of suppliers/ producers. For instance, in the agro/ food sector.

This kind of difference in the market situation has no influence on the interpretation of ILAC-P15 A n1.; Inspection Bodies and its inspectors shall not be engaged with the items inspected as

mentioned on the scope of accreditation, thus in general and not restricted to only the specific/ unique/ individual items that are subject of an inspection by the Inspection Body.

4- Type A / Type C

- It may be difficult to comply with the Type A independence requirements A.1b and A.1c in some sectors of economic activity where potential external inspectors in those sectors are, in most cases, engaged with the items inspected; In such cases Type C is an alternative for Type A.
- It should be noted that the impartiality and competence requirements for Type A and Type C are the same; only the independence requirements are different.

8. REFERENCES

- 6.1 ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles.
- 6.2 ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- 6.3 ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection.
- 6.4 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- 6.5 ISO 15189:2012 Medical laboratories – Requirements for quality and competence
- 6.6 ISO 9001:2015 Quality management systems – Requirements
- 6.7 IAF/ILAC A2:01/2018 IAF/ILAC Multi-lateral mutual recognition arrangements (Arrangements): Requirements and procedures for evaluation of a single accreditation body
- 6.8 ISO/IEC 17007:2009 Conformity assessment - Guidance for drafting normative documents suitable for use for conformity assessment
- 6.9 ILAC P8:03/2019 ILAC Mutual recognition arrangement (Arrangement): Supplementary requirements for the use of accreditation symbols and for claims of accreditation status by Accredited Conformity Assessment Bodies
- 6.10 ILAC P10:01/2013 ILAC policy on traceability of measurement results
- 6.11 ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments
- 6.12 ILAC G27:06/2017 Guidance on measurements performed as part of an inspection process
- 6.13 ILAC G28:07/2018 Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies