

# Application of ISO/IEC 17020:2012



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Tohu Matatau Aotearoa

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## Specific Criteria for Accreditation

# Application of ISO/IEC 17020:2012 for accreditation of inspection bodies in New Zealand

Incorporating ILAC P15 requirements and IANZ Notes

## AS IB C1

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## 1. Introduction

International Accreditation New Zealand (IANZ) Specific Criteria amplify or particularise IANZ's generic accreditation criteria for specific fields of technology. A list of all published Criteria is available from IANZ on request.

This document has been prepared as a companion to the primary criteria for accreditation of inspection bodies, ISO/IEC 17020:2012 *Conformity Assessment – Requirements for the operation of various types of bodies performing inspection*.

There are two distinct types of content in this document, internationally agreed interpretations and IANZ specific comments and expectations.

IANZ is the New Zealand national accreditation body for the accreditation of inspection bodies and a signatory to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA). This is a worldwide arrangement whereby inspection, and test reports and certificates, endorsed with the IANZ symbol, are recognised by all signatories as being of equivalent technical validity and reliability. There are currently over 80 signatories to the arrangement, providing significant added value to endorsed results when used to support global trade.

To achieve consistency of accreditation in different economies it is a condition of signatory status in the ILAC MRA that all signatory accreditation bodies must apply the published ILAC requirements documents related to the application of the international standards used as primary criteria for accreditation. In the case of inspection bodies, the relevant publication is ILAC P15:05/2020 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*. This Specific Criteria for Accreditation incorporates the text of ILAC P15 in its entirety. ILAC P15 requirements in this document must therefore be considered to be conditions of accreditation to ISO/IEC 17020:2012.

In addition, this document includes IANZ specific notes. These are not requirements of accreditation but they represent customary practice in New Zealand and provide clarification of meaning to clauses of ISO/IEC 17020:2012. IANZ notes provide good practice guidance for inspection bodies to clarify what will be expected of inspection bodies that seek accreditation to ISO/IEC 17020:2012. If an inspection body chooses not to follow the guidance directly it is their responsibility to demonstrate that their chosen procedure or practice is as good as or better than that outlined in the guidance.

In this document, the text of ILAC P15 (reproduced in its entirety) is presented in sections 2, 3 and 4. IANZ notes are presented in in text boxes to differentiate the IANZ guidance from mandatory ILAC P15 text.

For convenience of cross referencing, the numbering and formatting of this document is related directly to the section and clause numbers of ISO/IEC 17020:2012. For example, text numbered 5.1.3a relates directly to clause 5.1.3 of ISO/IEC 17020:2012. Section numbers in this document do not run consecutively as there may be no clarification or notes for some clauses of the Standard.

The term “shall” is used throughout this document to indicate those provisions which, reflecting the requirements and intent of ISO/IEC 17020:2012, or in a few cases requirements for the operation of accreditation bodies in ISO/IEC 17011, are considered to be mandatory for accreditation. The term “should” is used to indicate those provisions which, although not mandatory, are provided by ILAC as a recognized means of meeting a requirement. Inspection bodies whose systems do not follow the ILAC guidance will only be eligible for accreditation if they can demonstrate to the accreditation body that their preferred solution meets the intent of the relevant clause of ISO/IEC 17020:2012 in an equivalent or better way than that specified in this document.

## 2. 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”.

IANZ Note to 3.7:

Regulatory requirements over and above the requirements of ISO/IEC 17020:2012 constitute an inspection scheme.

### 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.

IANZ Note to the note following 4.1.3:

Examples of relationships that could influence 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 organisation(s) designing, manufacturing, supplying, installing, purchasing, owning, using or maintaining the items inspected

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.

IANZ Note to 4.1.4:

Inspection bodies should have policy and procedure to require all personnel to be aware of potential conflicts of interest at the organisational and personal levels and that any real, potential or perceived conflicts of interest that are identified should be recorded together with decisions on the elimination or minimisation of the effect of the identified issue.

Examples of such events, include, but are not limited to:

- employment of new personnel
- new contracts/clients
- subcontracting
- mergers
- acquisitions, etc.

(See also 6.1.12n1).

- 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.

IANZ Note 1 to 4.1.6:

It is the responsibility of the inspection body to provide all necessary information to support a decision on independence type A, B or C. The recommended method is to provide a completed "Independence Type Assessment Form" (available on the IANZ website) together with supporting evidence.

IANZ Note 2 to 4.1.6

It is an accreditation body's responsibility to make final decisions on the independence type of an inspection body for the entire scope or discrete parts of the scope. Independence type decisions are based on available information. IANZ is under no obligation to grant or continue the independence type requested by an inspection body if the information available to IANZ does not justify this.



#### IANZ Note 3 to 4.1.6

Designation of an inspection body as Type A, B or C is not a one-off event. Circumstances may change and an accredited inspection body should have a procedure to re-visit this decision at least annually, and whenever anything changes that could affect their independence Type.

Examples of circumstances that could affect the Type designation include but are not limited to:

- The inspection body (or its parent company) being bought by or merged with another organisation that has any interest in the types of items inspected,
- The inspection body (or its parent company) purchasing or merging with another organisation that has some involvement with the types of items inspected,
- The recruitment of new personnel who may have pre-existing relationships that may compromise independence,
- The inspection body or its personnel providing consultancy services to inspection clients,
- The inspection body or any related organisation or any of its personnel becoming involved in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the types of items inspected.

See Annex A (An1) for an explanation of the term 'items inspected'.

Changes of circumstances such as, but not limited to, those listed above do not necessarily change the independence Type A,B,C designation of the inspection body but they should be acknowledged, recorded and investigated for their possible effects and any actions taken to mitigate possible effects should be recorded for review by IANZ.

Inspection Bodies are encouraged to proactively consider factors that could affect their independence type before making business decisions to avoid potentially undesirable consequences.

Some changes of circumstances may be considered 'significant changes' that an inspection body is required to communicate to IANZ between scheduled assessments.

Failure to disclose relevant information could have serious consequences. If IANZ becomes aware, by any means, of relevant information that has not been disclosed by an inspection body an investigation will occur that could result in a change of independence type or, in a worst-case situation, the withdrawal of accreditation.

#### IANZ Note to 4.2.1:

It is implicit that this requirement must also be applied by the inspection body to any subcontractors or individuals acting on its behalf. The term "legally enforceable" in 4.2.1 means that confidentiality requirements to meet this clause should be included in contracts with all individuals, clients and subcontracted organisations. The inspection body is responsible for the actions of all persons acting on their behalf including subcontractors.

## **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.

#### IANZ Note to 5.1.3:

If an accredited inspection body makes claims of competence in publicity material, websites, etc. that are wider than the accredited scope they are required to clearly differentiate accredited from non-accredited activities to avoid committing an offence.

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 operations.

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.

IANZ Note 1 to 5.1.4:

An example of a consideration when determining what constitutes "adequate provision" would be advice from insurance advisor/provider following clear and recorded disclosure of the inspection body's activities.

When an inspection body chooses to rely on reserves, rather than insurance, IANZ will require evidence of the arrangement such as a statutory declaration from the organisation to provide confidence in the long-term availability of the declared reserves.

IANZ Note 2 to 5.1.4:

It is the inspection body's responsibility to ensure that clause 5.1.4 is complied with for all personnel acting on its behalf, including contractors, subcontractors and any other persons not directly employed by the inspection body. This responsibility includes run-out cover for professional indemnity when a person no longer works for the inspection body, where relevant.

IANZ Note to 5.1.5:

In the case of a Type C inspection body conditions of contract should include a clear statement of the issues that prevent it being classified as a Type A inspection body to allow clients to make informed decisions on the level of independence offered.

## 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.

IANZ Note to 5.2.2:

Other proposed means of maintaining competence in infrequently performed inspections will be considered on a case-by-case basis.

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 [to the inspection body].
- 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.

IANZ Note 1 to 5.2.5:

Part of a Technical Manager’s competence should be awareness of the legal and regulatory environment in which the inspection body operates. Where an inspection body’s technical manager is located overseas there may be a need for a local person to be appointed to ensure compliance with New Zealand specific requirements.

IANZ Note 2 to 5.2.5:

The words, “have available”, in clause 5.2.5, imply “contactable” whenever technical support may be needed, such as whenever inspections are taking place.

- 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.

IANZ Note to 5.2.6:

Clearly documented procedures for selecting and appointing competent deputies, rather than pre-naming deputies, may be considered on a case-by-case basis.

- 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 5.2.7 n1.

## Resource requirements - Personnel

- 6.1.1 n1 Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3 n1. 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.

IANZ Note 1 to 6.1.1:

Experience and the completion of training do not guarantee practical competence in inspection or the development of sound professional judgment. Therefore a list of qualifications and minimum length of experience, alone, will not be accepted as a definition of competence.

**IANZ Note 2 to 6.1.1**

Where relevant, inspection bodies should recognise that inspection categories described in the accreditation scope include sub-categories of items inspected, each of which have specific competency requirements. In some areas, inspection bodies will need to define and sub-divide the scope categories further than what is included on the accreditation scope document. For training and authorisation purposes, inspection bodies are encouraged to sub-divide the scope categories to ensure that an inspector has all the competencies required for each sub-category before being authorised to carry out that type of inspection, at a specified level of supervision.

6.1.1 n2 For “personnel involved in inspection activities”, see 5.2.7 n1.

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.

**IANZ Note 1 to 6.1.3:**

‘Appropriate’ qualifications, etc. may be specified in scheme rules such as regulations or in IANZ documents for specific technical fields.

**IANZ Note 2 to 6.1.3:**

Clause 6.1.3 applies to technical managers as well as inspectors.

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.

**IANZ Note to 6.1.5:**

Records of training and authorisation should be retained for a **minimum** of four years after the end of authorisation or for the duration of the currency of the reports/certificates produced by the individual, whichever is longer. If longer periods of retention are required in scheme rules these requirements must also be met.

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 5.2.7 n1.

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 6.1.9 n1. 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.

IANZ Note 1 to 6.1.9:

The frequency of monitoring expressed in 6.1.9 n2 above applies to each major area of inspection. Individuals involved in more than one inspection activity shall be monitored performing each major inspection activity they are involved in, at least once every accreditation cycle. See IANZ Note to 6.1.8

IANZ Note 2 to 6.1.9:

Where a ‘major area of inspection’ covers a number of different types of inspection of varying complexity, the monitoring scheme shall require witnessing of different types of inspection within that area, over time, with preference being given to more complex inspections within the area under consideration.

IANZ Note 3 to 6.1.9:

The term “competently” in clause 6.1.9 is intended to include both technical reliability and consistency with other inspectors in the same inspection body.

IANZ Note 4 to 6.1.9:

Records of monitoring must include details of what was observed with commentary on performance including any differences noted between individuals to facilitate actions to improve consistency of outcomes within the inspection body.

IANZ Note 5 to 6.1.9:

The intent of the Standard is that on-site observation should be the default and primary means of monitoring. It may be supplemented by other evidence. To be acceptable for accreditation, any proposed monitoring scheme that does not include on-site observation must be able to demonstrate an equivalent level of confidence in the continuing technical reliability and consistency of each inspector's work to that which could have been obtained from on-site observation.

IANZ Note 6 to 6.1.9:

Only in exceptional circumstances will witnessing performed by a personnel certification body be accepted and then only from ISO 17024 accredited bodies. In all cases, the inspection body must demonstrate that person(s) witnessing inspections meet the requirements of 6.1.8.

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

IANZ Note to 6.1.10:

Training records may be sufficient evidence to justify authorisation decisions if they contain sufficient detail and can demonstrate on-going compliance with defined competency criteria.

IANZ Note to 6.1.11:

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

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

IANZ Note 1 to 6.2.1:

Equipment required to carry out inspection in a safe manner may include but are not limited to personal protective equipment, environmental monitoring instruments, and access equipment.

IANZ Note 2 to 6.2.1:

Where safety equipment such as gas detectors, radiation monitors, harnesses, fall arrestors, etc. are essential, periodic calibration, testing, inspection or other means of validation may be needed to confirm on-going suitability and adequacy.

- 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.

IANZ Note 1 to 6.2.4:

Equipment, referred to in 6.2.4, may include software, controlled environment monitoring instruments and anything else that could significantly influence the outcome of inspections.

IANZ Note 2 to 6.2.4:

Decisions and the reasons for decisions on which instruments have, or do not have, a significant influence on the results of inspection should be documented to enable IANZ to review these decisions for appropriateness. These records also provide valuable institutional memory for inspection bodies.

- 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.

IANZ Note to 6.2.6 n2:

Copies of ILAC documents are available from IANZ on request or direct from the ILAC website, [www.ILAC.org](http://www.ILAC.org)

- 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 [of ISO/IEC 17011:2004] 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.



IANZ Note 1 to 6.2.7:

Traceable measurements should be the default for all measurements that may influence the outcome of inspections. IANZ requires accredited inspection bodies to record the rationale for any decisions regarding the non-applicability of traceability to national or international standards of measurement.

Metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”.

Metrological traceability is established by considering, and then ensuring, the following:

- a) the specification of the measurand (quantity to be measured);
- b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);
- c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods;
- d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties;
- e) that the laboratories performing one or more steps in the chain supply evidence for their technical competence.

IANZ Note 2 to 6.2.7:

In the situation where an inspection body has established that a measurement is critical, the instrument(s) used for the measurement must be traceably calibrated if that is possible.

IANZ Note 3 to 6.2.7:

If an inspection body chooses to perform in-house calibration of working instruments, that require traceable calibration, IANZ will assess the inspection body's competence to perform traceable calibrations on the basis of witnessing calibrations and the following information and any other information that may be relevant for a particular calibration.

- Records of calibration method validation
- Procedures for estimation of uncertainty
- Documentation for traceability of measurements (traceable calibration of reference instruments, artefacts or materials)
- Documentation for assuring the quality of calibration results
- Documentation for competence of staff in calibration
- Documentation for accommodation and environmental conditions (if relevant)
- Audits of the calibration function by a person competent in calibration

IANZ reserves the right to require a specialist calibration technical expert to be included in an assessment team when an inspection body performs in-house calibration.

6.2.7 n2 The preferred routes for inspection bodies who seek external services for calibration of their equipment are defined in ILAC P10.



IANZ Note 4 to 6.2.7:

The ILAC preferred means of calibration, as set out in section 2 of ILAC P10, are as follows:

- 1) A National Measurement Institute (NMI) whose service is suitable for the intended need and is covered by the CIPM MRA. (The Measurement Standards Laboratory of New Zealand (MSL) is the New Zealand NMI ).
- 2) An ISO/IEC 17025 accredited calibration laboratory whose service is suitable for the intended need (i.e., the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the ILAC Arrangement.
- 3a) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. In this case the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2005.
- 3b) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement. In these cases the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.

IANZ requires accredited inspection bodies to record the justification for any decisions to use routes 3a) or 3b) of section 2 of ILAC P10.

IANZ will not accept calibrations from 3a or 3b sources unless it has been established that calibration is not available from sources 1 or 2.

In-house calibrations are considered to be equivalent to ILAC P10 option 3b, unless the calibration laboratory is ISO/IEC 17025 accredited for the specific calibrations, and should only be employed where ILAC P10 options 1 and 2 are not possible.

IANZ can provide advice on sources of traceable calibration in New Zealand and worldwide on request.

- 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.

IANZ Note to 6.2.9:

By default all equipment defined under clause 6.2.4 as having a significant effect on the outcome of inspections, should be subject to in-service checks. Decisions not to perform in-service checks for equipment that could affect the outcome of an inspection must be justified and documented.

- 6.2.10 n1 The information provided in 6.2.7 n1, 6.2.7 n2 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.

IANZ Note 1 to 6.2.13:

Clause 6.2.13 applies to all uses of computers including but not limited to the generation, storage and communication of inspection records, reports, certificates, quality management system documentation and records of the implementation of the quality management system.

IANZ Note 2 to 6.2.13:

The term 'computers or automated equipment' in clause 6.2.13 includes mobile devices such as tablets, smart phones, data loggers or other devices used to generate, record, store or communicate data critical to inspection outcomes.

Data may include, but is not limited to, measurements, photographs, video, sound recordings, spatial data e.g. from GPS or GIS, templates, checklists, etc.

IANZ Note to 6.2.13 b:

Factors that should be considered in protecting the integrity and security of data include:

- Backup practices and frequencies,
- Effectiveness in restoring data from backup,
- Up to date protection from viruses and other malware including ransomware,
- Password protection,
- Data encryption (prevent theft/copying),
- Security against loss (deletion or corruption),
- Management of long term storage issues e.g. changes of operating systems, software, file formats and storage media,
- Contingency plans for disaster recovery including loss of connectivity,
- Password protection,
- Legal protection of data (particularly in cloud storage)
- Personnel IT security training.

## Resource requirements - Subcontracting

IANZ Note to 6.3 (subcontracting in general):

ISO/IEC 17020:2012 refers to an inspection body **contracting** to perform **inspections**.

For accreditation purposes the term 'inspection', in this context, means all activities that contribute to the issue of a **single report** or certificate relating to a specified item inspected. Examples of items inspected include a crane, a pressure vessel, a food control plan, a fire sprinkler system, a property, a vehicle, an offshore installation, etc. A 'single inspection' as clarified here, may consist of many subsidiary inspection and/or testing activities but in all cases the report or certificate refers to the defined item inspected.

For accreditation purposes the term '**contract**' refers to an agreement between an inspection body and a client to provide inspection services. A contract may cover multiple 'inspections'. A contract may include unaccredited inspections and other services, however these must be clearly differentiated in the contract and in the issued report.

For accreditation purposes a **subcontract** exists when an inspection body agrees to provide, and receive payment for, services that it cannot fully provide itself but organises for another organisation to deliver the service on the inspection body's behalf. Critically the inspection body must use the subcontracted inspection results to make the conformity decision that is covered by the inspection body's accreditation and IANZ endorsement (see clause 6.3.3).

A note on what is NOT subcontracting:

An arrangement whereby an inspection body puts a client in touch with another service provider but does not charge the client for the service and does not make the conformity decision and does not report the results to the client is not a subcontract arrangement and is not subject to the requirements of section 6.3

If some or all of the inspections included in a contract are outside of the accredited inspection body's current scope of accreditation the inspection body shall clearly inform the client, before the contract is agreed, that they cannot provide IANZ endorsed reports/certificates for those inspections that are outside of their current scope of accreditation.

- 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.

IANZ Note to 6.3.1 n1:

If an inspection body loses all of its personnel that are authorised to perform a specified type of inspection then its accreditation for those inspections is **automatically** suspended until competent individuals are available, trained, and authorised as signatories.

This is a significant event and the inspection body is required to inform IANZ immediately when a loss of capability takes place, so that the published scope can be updated. During suspension, for any reason, an inspection body cannot issue endorsed reports for the suspended scope and therefore the inspection body cannot endorse reports based on subcontracted work for the suspended part of their scope.

IANZ Note 1 to 6.3.1:

Subcontracting, of any particular type of inspection, must be the exception rather than the normal situation. The intent of ISO/IEC 17020:2012 is that clients of accredited inspection bodies should have a reasonable expectation that the inspection body they contract, and pay, for an inspection, will, themselves, perform the inspection.

IANZ Note 2 to 6.3.1:

The wording of 6.3.1 requires an inspection body to decide which conformity assessment Standard is appropriate for subcontracted work and what are the 'relevant' requirements in the chosen Standard. To enable these important decisions to be assessed these decisions, and the rationale for the decisions, must be recorded and retained.

IANZ Note to 6.3.1 Note 1:

Some acceptable reasons for subcontracting and their limitations.

An unforeseen or abnormal overload is a situation in which the inspection body is accredited for the inspections in question and has the competence and capacity to perform its typical inspection workload, but an unexpected workload results in a temporary shortfall in capacity. Subcontracting is allowable for the inspection body to meet the extra inspections only. If the increased demand for inspection work continues, in the long term, subcontracting is not acceptable as a means of meeting the new 'normal' demand.

Key inspection staff members being incapacitated is limited to **temporary** unavailability of inspection personnel due to illness, injury, etc. This does not cover situations such as key personnel permanently leaving the inspection body, loss of personal certification, loss of authorisation or loss of accreditation.

To be accepted as '**temporary**' an inspection body should record how long the individual is reasonably expected to be incapacitated and what they plan to do if the expected period has to be extended. Indefinite extensions cannot be accepted as a temporary situation.

Part of the contract from the client involving inspection not covered by the inspection body's scope or being beyond the capability or resources of the inspection body. This reason for subcontracting only applies when the inspection body has the capability and resources to undertake a significant part of the contracted inspection work itself and when the inspection body has the competence and capacity to take **responsibility** for the subcontracted part of a larger inspection.

IANZ Note to 6.3.1 Note 2:

In all cases of subcontracting or outsourcing the work is carried out under the subcontractor's management system.

- 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.

IANZ Note to 6.3.3:

When an inspection body subcontracts an inspection that is limited to examination, the inspection body remains responsible for the quality, reliability and consistency of the examination and records provided by the subcontractor.

- 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.

IANZ Note to 6.3.4:

The requirements of clause 6.3.4 apply to all parties 'contracted' to provide services and results on which an inspection decision relies, whether legally contracted by the inspection body or by a third party such as the owner or operator of the inspected items. The inspection body remains responsible for the inspection result (6.3.3) and must therefore make a decision on the acceptability of the supplier based on recorded investigations (6.3.4).

## 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 n1 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.

### IANZ Note to 7.1.3:

Incorporating new technology into an existing inspection method or introducing a new inspection method, whether using new technology or not, e.g. remote assessments, constitutes a significant change in terms of the IANZ Procedures and Conditions for Accreditation clause 5.1(j) and therefore an inspection body must formally inform IANZ before introducing a new or significantly changed inspection method or technology. IANZ will decide whether or not any special assessment is required on a case-by-case basis.

- 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.

**IANZ Note to 7.1.6:**

Inspection bodies must make a decision on the reliance to be placed upon information supplied by any other party. An inspection body is not obliged to accept any information supplied by any other party. Reasons for accepting or not accepting information supplied by another party should be recorded.

**IANZ Note to 7.1.7:**

Worksheets, notebooks etc. used to record observations during inspections must be retained for a defined period of time. When defining a retention period inspection bodies must comply with any relevant scheme rules. Inspection bodies are also encouraged to consider the period of validity of reports/certificates, the value of records for their own defence, and their clients' convenience as well as the costs associated with storage. A minimum of four years is recommended for accreditation assessment purposes.

**IANZ Note to 7.1.8:**

The nature of checks should be defined, including their purpose and the point(s) in the process when they should take place. Records should be kept to demonstrate that checks have taken place and allow verification of the effectiveness of calculation and transcription checks.

## **Process requirements – Inspection records**

- 7.3.1 n1 The records should indicate which particular items of equipment, having a significant influence on the result of the inspection, have been used for each inspection activity.

## **Process requirements – Inspection reports and certificates**

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

**IANZ Note to 7.4.2 n1:**

Copies of ILAC documents are available from IANZ on request or direct from the ILAC website, [www.ilac.org](http://www.ilac.org). The IANZ rules for endorsement, which comply with ILAC P8, are to be found in the Procedures and Conditions for Accreditation document available on the IANZ website [www.ianz.govt.nz](http://www.ianz.govt.nz)

**IANZ Note 1 to 7.4.2c:**

Where an inspection report/certificate includes the results of many inspections, spanning a lengthy period of time, a statement of the relevant range of dates may be acceptable to meet the requirement of 7.4.2c provided supporting records identify the dates of each contributing inspection.

**IANZ Note 2 to 7.4.2c:**

IANZ may consider accepting a combined inspection/issue date on reports or certificates if an inspection body can make a convincing case that the date(s) of inspection are not critical. E.g., when items such as documents are the subject of the inspection and they cannot change following the inspection. If a combined date is to be used the meaning must be explicit on the report/certificate.

**IANZ Note to 7.4.4:**

It may be useful to identify the inspection method in the inspection report/certificate when this information helps to arrive at an appropriate interpretation of the reported inspection results.

## Management system requirements - Options

**IANZ Note to 8.1.1:**

Whichever option is chosen, compliance with the requirements of clauses 8.2 – 8.8 and 7.5 and 7.6 is a condition of accreditation. The inspection body must provide objective and impartial evidence of compliance with all requirements to the accreditation body to justify the granting of accreditation.

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 system is certified to ISO 9001. However, when determining the extent of assessment required, 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.

**IANZ Note to 8.1.3:**

If an inspection body chooses option B it has a responsibility to demonstrate that relevant parts of their ISO 9001 compliant system meet the requirements set out in clauses 8.2. to 8.8 and 7.5 and 7.6 of ISO/IEC 17020, some of which are more prescriptive than those in ISO 9001.

An inspection body that selects option B will be required to provide objective and impartial evidence that:

- its management systems are established (documented) and fully comply with ISO 9001, and
- its management systems are maintained up to date and appropriate, and
- its management systems are capable of fulfilling all requirements of ISO/IEC 17020:2012 (including those not explicit in ISO 9001) and
- its management systems consistently fulfil all requirements of ISO/IEC 17020:2012.

IANZ will review evidence of compliance with 8.1.3 presented in the form of a recent ISO 9001 audit report from an accredited certification body. If the report provides confidence that the inspection body meets all, or some, of the requirements of 8.1.3, as clarified in ILAC P15, IANZ may seek less direct evidence of compliance with those aspects of ISO/IEC 17020 than would be required of an inspection body that chose option A.

## Management system requirements – Management system documentation

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.

**IANZ Note to 8.3.1:**

The term ‘establish’ in clause 8.3.1 means that all policies and procedures needed to ensure compliance with the requirements of ISO/IEC 17020:2012 shall be documented and controlled.

The reason for this interpretation is that policies or procedures that are not documented and controlled cannot be reviewed, or audited. In addition, it is not possible to establish continuing consistency of operations if procedures are not fixed, at a given time and independently of existing personnel, so that personnel can be consistently trained in them and the possibility of un-authorised evolution of policies and procedures is prevented.



## Management system requirements – Control of records

- 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

- 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

### IANZ Note to 8.6.2:

Clause 8.6.2 is intended to encourage more targeted auditing of areas of higher risk or of known problem areas rather than justifying less auditing. (See 8.6.4)

### IANZ Note on internal auditing:

The intent of clauses 8.6.3 and 8.6.4 is that all procedures (all aspects of ISO/IEC 17020:2012) shall be audited annually as a minimum. 8.6.4 n1 allows organisations with multiple sites to spread their auditing across their sites with the intent that all procedures should be audited annually but that each procedure must be audited at each site at least once in an accreditation cycle.

### IANZ Note to 8.6.3:

An inspection body must be able to demonstrate how audits are planned, including the coverage of each aspect of ISO/IEC 17020:2012 and the frequency of audits of each aspect. (See IANZ Note to 8.6.4 for frequency considerations.)

- 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.

IANZ Note to 8.6.4 n2:

This note encourages inspection bodies to use the tool of internal auditing to ensure that the requirements of ISO/IEC 17020:2012 are consistently met on a day-to-day basis. If internal audits are effective and sufficiently frequent IANZ assessment time and therefore cost should be minimised.

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

## Management system requirements – Preventive actions

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.

IANZ Note to A1 (d)(1):

An inspection body having links to a separate legal entity that has interests in the type of items inspected by the inspection body **need** not prevent the inspection body from being designated as a Type A inspection body. In this situation an inspection body would have to provide **convincing evidence** that there was no possibility that a person or group of persons could influence the result of any inspection. Examples of potential influences that should be considered include but are not limited to:

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

## **Annex B: Optional elements of inspection reports and certificates**

### IANZ Note to Annex B:

The list of items (a) to (m) is not an exclusive list. Inspection bodies may add other relevant elements to reports and certificates provided they do not contravene any requirement of ISO/IEC 17020:2012, IANZ rules for endorsement, or scheme rules including relevant regulations, standards, etc.

### 3. Annex 1: Possible format for an impartiality risk analysis

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)?
<b>1. Activities of the inspection body</b>			
-			
-			
-			
<b>2. Relationships of the inspection body</b>			
-			
-			
-			
<b>3. Relationships of personnel</b>			
-			
-			
-			

Table 1. Possible format for an impartiality risk analysis

## 4. Annex 2: Relationship between impartiality and Type A independence requirements

- 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.1.c 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 their 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.

## 5. IANZ Position Statement on Independence of Inspection Bodies

### Preamble

ISO/IEC 17020:<sup>1</sup> requires all inspection decisions by accredited inspection bodies to be impartial.

ISO/IEC 17020:2012 also includes three independence categories for inspection bodies, Type A, B and C.

Independence and impartiality are different concepts that are closely linked and often confused.

This position statement focusses entirely on the independence aspects of ISO/IEC 17020:2012 and incorporates the internationally agreed interpretations of the standard published by International Laboratory Accreditation Cooperation (ILAC) in ILAC P15 <sup>2</sup>. The intent is to set out the aim of independence types and the interpretation of the standard that will be applied by IANZ assessors. This document is intended to help ISO/IEC 17020:2012 clients as well as IANZ assessors.

### Background

The intent of the three independence types in the standard is to provide a formal mechanism for identifying real, potential and perceived risks to independence, as a support for the overall impartiality of inspection decisions.

The ISO/IEC 17020:2012 requirements for independence type designation are documented in Clause 4.1.6 and Annex A of the standard.

Clause 4.1.6 states:

*“The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements stipulated in Annex A, as outlined below.”*

This clause means that the conditions under which an inspection body operates may include requirements to conform to Type A, or B or C requirements or may not. The conditions referred to here may be dictated by law (regulations), by national or international standards, by industry consensus (scheme rules), by contracts (client conditions) or by the inspection body's choice.

### Commentary

Some inspection bodies operate in environments where there is no stipulation that they must be Type A or B or C. This does not mean that an inspection body can ignore the independence type issue. Clause 1, second paragraph, of ISO/IEC 17020:2012 states:

*“It [ISO/IEC 17020:2012] applies to inspection bodies of type A, B or C, as defined in this International Standard and it applies to any stage of inspection.”*

This indicates that if an inspection body cannot demonstrate that it meets the independence requirements of Type A or B or C then it cannot claim compliance with the standard and therefore cannot be accredited to the standard.

Before considering the meaning of Annex A it is important to read and understand the ILAC P15 clarification of the meaning of ‘items inspected’. The international consensus is that the term ‘items inspected’ means the *class of items* described in the scope of accreditation of the inspection body, not just the specific member(s) of the class of items that the inspection body inspects.

This is most simply understood by reading the words “items inspected” as “**type** of items inspected”.

### Type A inspection bodies

Type A, third party, inspections are generally stipulated where there is a perceived need for true independence of inspection outcomes and where a high level of confidence is required that vested interests cannot influence the outcomes of inspections. The aim of providing this assurance is expressed in Annex A; A.1(a) which states:

*“The inspection body shall be independent of the parties involved.”*

Annex A; A.1(b – d)) provides more detail on what is meant by independence. The first sentence of Annex A A.1(b) states:

*“The inspection body and its personnel **shall** not engage in **any activities** that **may conflict** with their independence of judgment and integrity in relation to their inspection activities.”*

The “**shall**” in the sentence makes clear that what follows are requirements not just good practice or guidance.

The words “**any activities**” means that prohibited activities are not confined to the specific activities listed as examples.

The words “**may conflict**” mean any activities that could, conceivably, conflict with the independence of judgement or integrity of inspection activities; not just activities that can be shown to have actually affected inspection outcomes. A useful way of looking at what “may conflict” means is to consider the point of view of an outsider or competitor looking at the inspection body, rather than assuming that nothing conflicts.

The second sentence of Annex A A.1(b) provides a list of specific activities that a Type A inspection body or its personnel (including contractors) are not allowed to do if they wish to maintain Type A status. These are as follows:

- Designing the **type of items** they inspect (this includes providing related consultancy services).
- Manufacture of the **type of items** they inspect (this includes writing or consulting on system documentation as well as the manufacture of physical items or the building of property).
- Supplying the **type of items** they inspect (this includes selling and acting as an agent for vendors).
- Installing the **type of items** they inspect (this includes implementation of documented systems, provision of signage etc. as well as physical installations).
- Purchasing the **type of items** they inspect (this includes purchasing for supply and acting as an agent for purchasers).
- Owning the **type of items** they inspect (except for personal use or direct use by the inspection body).
- Maintaining the **type of items** they inspect (this includes contract quality management system functions such as internal auditing, management reviews, training of personnel and management of complaints, as well as management or control of the type of equipment or property inspected).

The list of specifically prohibited activities for Type A inspection bodies, is not comprehensive as it is impossible to know in advance all possible circumstances or business models that may be encountered. The first sentence of Annex A A.1(b) sets out the principles on which judgements should be based.

Note that there are no exceptions to Annex A A.1(b).

The text of sub-clause (c) states:

*“An inspection body **shall not** be a part of a legal entity that is engaged in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the [types of] items inspected.”*

A Type A inspection body may be part of a larger organisation but not one that has interests in the **type of** equipment, property, systems etc. that the inspection body inspects.

Note there are no exceptions to Annex A A.1(c)

Annex A A.1(d) states:

*“The inspection body **shall not be linked** to a separate legal entity engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected by the following: “*

The text of sub-clause (d), and its four specific cases, list particular ways in which an inspection body must not be linked to a separate legal entity that could have a vested interest in the outcome of inspections.

In all cases there are exemption clauses which focus on the ability of associated legal entities to influence the outcome of specific inspections. It is the responsibility of the inspection body to provide compelling evidence of the effectiveness of measures taken to make interference with inspection decisions impossible.

ILAC P15 Ab lists 5 specific areas in which influence could be brought to bear. As a minimum the issues listed should be explicitly addressed by the inspection body's policies and procedures.

Unsupported statements that individuals cannot influence the outcome of inspections will not be accepted.

### Type B inspection bodies

A Type B inspection body is, by definition, part of an organisation that does have an interest in the type of items inspected.

The inspection body, including all of the inspection personnel and management, must be demonstrably independent of the functions and personnel of the parent organisation which could have reason to seek to influence the outcome of inspections.

The same wording of "any activities" and "may conflict" are used and therefore the same rigour must be applied to consideration of possible influences on inspection outcomes in a Type B inspection body as in a Type A inspection body. The same list of specific independence issues applies to Type B inspection bodies as to Type A inspection bodies. It may be more difficult to establish confidence in the independence of a Type B inspection body as it is difficult to identify and control informal routes of influence between individuals within a single organisation. Examples could include situations where personnel move from production to inspection roles or vice versa.

Type B inspection bodies are not allowed to offer inspection services to any organisation except the organisation of which they form a part. However, a Type B inspection body may perform second party inspections. A second party inspection is, by definition, an inspection performed on a supplier by a customer or by a contracted organization on behalf of a customer. A Type B inspection body may perform inspections external to its parent organisation but only on behalf of its parent organisation. A corollary of this is that a Type B inspection body cannot perform second party inspections of its parent company's products or services on behalf of an external client.

### Type C inspection bodies

A Type C inspection body is, by definition, part of an organisation that does have an interest in the type of items inspected.

The inspection body, including all of the inspection personnel and management, must be demonstrably independent of the functions and personnel of the parent organisation which could have reason to seek to influence the outcome of inspections.

ISO/IEC 17020:2012 Annex A A.3(b) does not allow any individual to be involved in inspection if they are also involved in the design/manufacture/supply/installation/servicing/maintenance and the inspection of the same item (unless there is a regulatory exemption from this requirement).

An inspector in a Type C inspection body may inspect items designed, manufactured, supplied, installed, serviced or maintained by the inspection body's parent organisation. Type C inspection bodies cannot claim to perform third party independent inspections.

A Type C inspection body will be expected to have effective policies and procedures in place to separate information gained from external clients from interested parties within its parent organisation.

## Illustrative Examples

### Example 1

An organisation wishing to be a **Type A** inspection body to inspect houses, e.g. for weather tightness, methamphetamine or asbestos, cannot have any interest in the properties they inspect OR any other property which could conceivably be in competition with properties in which they hold an interest.

If an inspection body was allowed to inspect properties that were in the same market as properties that the inspection body or its personnel or its associates had an interest in the inspection body could be suspected of biasing inspection results for or against properties depending on the inspection body's or its associates' vested interests.



## Example 2

An inspection body that wishes to be a Ministry for Primary Industries (MPI) recognised evaluation and/or verification agency is required by regulation to be a Type A inspection body. However; to meet the requirements of Type A an inspection body that evaluates or verifies Food Control Plans (FCP) cannot be involved in, the design, drafting, sale, implementation, management or maintenance of FCPs, not limited to those they evaluate or verify.

## References

1. ISO/IEC 17020:2012: *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*
2. ILAC P15:05/2020 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*