



Specific Criteria for Accreditation Specific Procedures and Conditions for Inspection Body Accreditation

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AS IB C2

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Building 7, Central Park, 660-670 Great South Road, Ellerslie, Auckland 1051

Private Bag 28908, Remuera, Auckland 1541, New Zealand

Telephone: +64 9 525 6655

Email: info@ianz.govt.nz

Internet: www.ianz.govt.nz

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Contents

1	Introduction	6
2	Accreditation Standards.....	6
3	Accreditation Procedures	6
3.1	Initial accreditation process.....	6
3.2	International standard requirements for initial assessments	8
3.3	Application documentation review	8
3.4	Pre-assessment meeting or site visit	8
3.5	Assessment team briefing and technical document review.....	9
3.6	On-site assessments.....	10
3.6.1	Initial assessments	10
3.6.2	Witnessing inspections.....	10
3.6.3	Assessment Report	11
3.7	Maintaining accreditation	11
3.7.1	Routine reassessment.....	11
3.7.2	Surveillance assessments.....	12
4	Approval and Endorsement of Inspection Reports and Certificates	14
4.1	Approval of inspection reports and certificates.....	14
4.2	Endorsement of Inspections	14
	Appendix 1: Key Staff and Approved Signatories.....	16
	Appendix 2: Signatory Assessment	19
	Appendix 3: Multi-site Accreditation	21
	Appendix 4: Scopes of Accreditation	22
	Appendix 5: Assessment Sampling.....	24
	Appendix 6: Equipment Calibration and Traceability	25

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 IANZ general criteria for accreditation document *Procedures and Conditions for Accreditation* (AS 1), which describes the structure of IANZ, the general IANZ accreditation processes, and rules for accredited organisations across all IANZ accreditation programmes, including the inspection body accreditation programme.

It includes additional descriptions of the IANZ accreditation processes specific to the inspection body accreditation programme, and additional clarification of the rules for accredited inspection bodies.

This document must be read in conjunction with the current edition of *Procedures and Conditions for Accreditation* (AS 1).

2 Accreditation Standards

ISO/IEC 17020: *Conformity assessment - Requirements for the operation of various types of bodies performing inspection* is used by accreditation bodies worldwide for the accreditation of inspection bodies and is the agreed international standard that forms the basis of Mutual Recognition Arrangements (MRAs).

To ensure global consistency, international co-operations of accreditation bodies (such as the International Laboratory Accreditation Cooperation (ILAC) of which IANZ is a member) have agreed applications of ISO/IEC 17020. These applications have been published in support of international MRAs and are applied by IANZ e.g. ILAC P15:06/2014 – *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*.

IANZ has republished ILAC P15/2014 in its entirety, and incorporating additional IANZ guidance, as a Specific Criteria for Accreditation document *Application of ISO/IEC 17020:2012* (AS IB C1). This document is a requirements document for inspection bodies seeking and maintaining accreditation with IANZ.

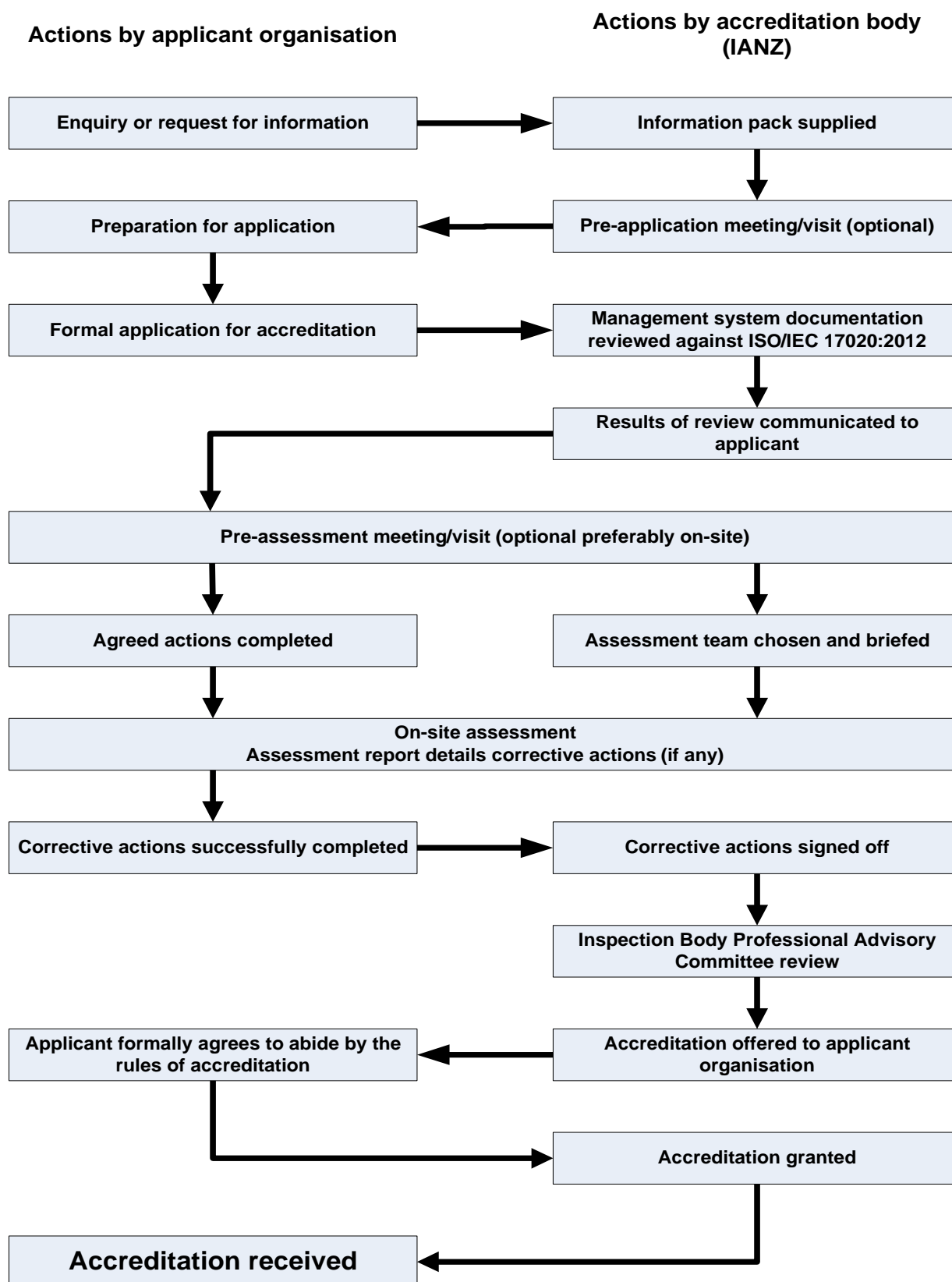
3 Accreditation Procedures

Section 4 of *Procedures and Conditions for Accreditation* (AS 1) sets out the accreditation process for all IANZ accreditation programmes and are applied by IANZ in the accreditation of inspection bodies. The following procedures expand upon these are as specific to the demands of inspection body accreditation.

3.1 Initial accreditation process

A schematic overview of the initial accreditation process is shown in the Figure 1. Each step in the process is described in Section 4 of *Procedures and Conditions for Accreditation* (AS 1), and/or in the text following.

Figure 1: Initial accreditation process



3.2 International standard requirements for initial assessments

Accreditation bodies operate in accordance with ISO/IEC 17011 which includes the following requirements for initial assessment of inspection bodies.

1. All locations from which one or more key activities are performed and which are covered by the scope of accreditation must be visited and assessed during an initial assessment.
2. The assessment team must witness a representative sample of the work being undertaken by the inspection body in order to ensure proper evaluation of the competence of the organisation to undertake the inspection activities proposed for accreditation.

The determination by IANZ of a 'representative sample of the work' will be conducted on a case-by-case basis taking into consideration the following factors:

- The nature and number of locations to be visited,
- The number of Approved Signatories/Key Technical Personnel/Competent Persons to be assessed and the scope of their authorisation(s),
- The requested scope of accreditation of the applicant organisation.

The internationally accepted interpretation of ISO/IEC 17011 also requires IANZ to select particular inspection body personnel to be witnessed performing work covered by the scope of accreditation. In choosing which persons to witness IANZ must take into account factors such as new inexperienced employees, the risks and the complexity of the inspection activity, the physical capabilities of staff and any other factors considered relevant. The circumstances of the inspection body including the availability of specific types of work and practical considerations such as accessibility will also be taken into consideration in these decisions. For accredited inspection bodies IANZ must be able to demonstrate, to overseas peers, that the whole accredited scope and all locations where key activities are performed are assessed during each accreditation cycle (normally 4 years).

3.3 Application documentation review

The applicant is required to indicate in their application the scope of their requested accreditation. In situations where IANZ approved signatories are relevant, the assessment team will assess whether sufficient information has been provided for each applicant signatory. The scope of the assessment is established by the assessment team after a review of all the signatory applications.

In situations where IANZ assesses a sample of personnel as a means of assessing the inspection body's systems for authorising signatories the situation is different. The inspection body is required to supply a list of all types of work carried out by the organisation for which accreditation is sought, along with a list of all personnel performing each type of work (both those authorised by the inspection body and those under training).

When substantial compliance of documentation with accreditation requirements has been demonstrated to the satisfaction of the Lead Assessor, a pre-assessment meeting may be arranged with the applicant.

3.4 Pre-assessment meeting or site visit

Following the completion of the application documentation review, and prior to arranging the on-site assessment, a pre-assessment meeting may be arranged between the Lead Assessor and inspection body staff. The purpose of this meeting is to discuss and agree practical details of the assessment and to prepare the inspection body's personnel and the lead assessor for the assessment. Subjects covered normally include but are not limited to;

- any issues arising from document review,
- scoping issues,
- proposed assessment dates and locations,
- proposed Technical Experts,
- types and locations of inspection work to be witnessed,
- health and safety requirements for team members (personal protective equipment etc.),

- actions to be undertaken by IANZ before the initial assessment,
- actions to be undertaken by the inspection body before the initial assessment,
- briefing inspection body personnel who will be involved in the assessment,
- any questions from inspection body personnel.

To gain maximum benefit from this meeting it is recommended that it take place at the premises of the inspection body and that as many relevant inspection body staff as possible attend for all or at least relevant parts of the meeting. It is particularly beneficial for the Authorised Representative, the Technical Manager, the Quality Manager and as many inspection staff as possible to meet the Lead Assessor before the initial assessment. In larger organisations it may also be beneficial for representatives of other departments, such as human resources, information technology, records management, customer services, etc. to meet the Lead Assessor. This is because issues managed by other departments may be raised during the assessment and records controlled by other departments may be requested. If heads of these departments are not aware of this before the on-site assessment there could be delays in accessing people, records etc and subsequent delays in the accreditation process.

If the inspection body uses part time or contracted personnel the required level of access to these people for the initial assessment will be discussed during the pre-assessment meeting.

At the end of the pre-assessment meeting it should be clear what actions are required of both parties before the on-site assessment can take place. It should also be clear approximately when the assessment will take place, which locations will be visited, what type of inspections or other activities must be witnessed etc. It is the responsibility of the applicant inspection body to arrange suitable activities for the team to witness in order to adequately assess the full scope of work.

A pre-assessment meeting normally involves a single IANZ staff member and lasts between a half and a full day. The greater number of the organisation's personnel that are able to meet the IANZ representative and become informed and comfortable with the assessment process the smoother the assessment is likely to proceed. Pre-assessment meetings are charged according to IANZ' current fee schedule.

3.5 Assessment team briefing and technical document review

Following their formal appointment and prior to the on-site assessment, each team member will receive briefing material. This will include copies of relevant procedures, work instructions, example worksheets and reports, equipment records, staff training records including inspector monitoring (peer review) records and selected management system records.

To allow sufficient time for preparation of briefing material, and for team members to review the material, requested documents and records shall be provided to the Lead Assessor at least one month before the agreed assessment date.

The Technical Expert(s) will review the briefing material to become familiar with the organisation's methods, to assess the technical validity of procedures, the suitability of equipment and to prepare for the interview of staff and witnessing of inspection activities. Experts may request further information at this stage. Such requests and any responses must be via the IANZ Lead Assessor. It is inappropriate for inspection body staff and experts, engaged by IANZ for an assessment, to enter into private discussions without the knowledge and control of the lead assessor.

If issues are identified, during the technical document review, which raise significant doubts about the readiness of the inspection body for an initial assessment, the inspection body will be informed and requested to respond. If there are significant delays in resolving these issues it may be necessary to postpone the agreed date of the initial assessment.

3.6 On-site assessments

3.6.1 Initial assessments

All locations, from which one or more key activities are performed and which are covered by the scope of accreditation, must be visited and assessed during the initial assessment process.

Key activities include;

- policy formulation,
- process and/or procedure development,
- process of initial selection of inspectors,
- review of new work or contracts,
- planning inspection work,
- review and approval of inspection reports/certificates.

During its on-site visit(s) the assessment team will focus on the technical operations, the management system, the competence of staff and on the inspection methods, equipment and facilities used. The team will need to witness inspections and other activities relevant to the scope. Information will also be gathered from review of records and discussions with personnel involved in all activities related to inspection work and its management.

3.6.2 Witnessing inspections

Witnessing is an essential component of accreditation assessments as it provides objective evidence of the effective implementation of the documented systems and that the organisation is capable of producing consistently reliable inspection results in compliance with accreditation requirements.

A representative sample of activities, covering the requested scope of accreditation, must be witnessed. Inspection activities are normally witnessed by the specialist expert and an IANZ assessor but in some circumstances an expert may witness inspection activities alone.

Witnessing may be undertaken as an integral part of the on-site assessment visit or may be organised at a different date and time to suit the circumstances.

Each person to be witnessed will be briefed regarding the witnessing process so that expectations are clear. Included in this briefing will be an explanation that IANZ is primarily assessing the organisation's systems rather than the individual that is demonstrating the implementation of the systems and procedures.

In some cases it may not be practicable or cost effective, to witness an entire inspection during the assessment process. In these cases the scope and extent of activities to be witnessed will be agreed with the person being witnessed. As an example, if an inspection process involves many repetitions of a particular activity a team member may suggest that the inspector move on to the next stage before completing all of the repetitions that would normally take place.

It is important that team members do not prompt the inspector in any way that could affect the conclusions drawn. The only exception to this being if an inspector is seen to be acting in such a way that the safety of the inspector, the client's staff, the product being inspected or the public, may be jeopardised. In such cases members of the assessment team may intervene as they have a duty of care.

Team members will take notes during witnessing and may subsequently request copies of on-site notes made by the witnessed person(s) during the witnessed work and a copy of the report, certificate or correspondence arising from the witnessed inspection. Conclusions drawn from witnessing may reflect on the recruitment process, the training system, supervision arrangements or other aspects of the organisation's management systems or the competence of the inspector. One component of witnessing is confirming that the witnessed individual has the level of competence attested to by the organisation's competence assessment system.

3.6.3 Assessment Report

In addition to the classification of assessment findings and observations into Nonconformities (NCs) and Comments, the inspection body accreditation programme has the following additional classification:

- **Supplementary Information Requests (SIRs)** are requests for additional information identified during the assessment. A typical example being a copy of the field notes and report/certificate related to a witnessed inspection. A SIR does not imply a non-conformance; however satisfactory information is required in response to an SIR before the assessment can be closed.

3.7 Maintaining accreditation

Following initial assessment and subsequent accreditation, accredited inspection bodies are subjected to periodic assessment as a condition of continuing accreditation. The rules for coverage of scope, locations to be visited and the witnessing of inspection related activities are the same as for initial assessments.

These on-going assessments include the following basic elements;

- review of technical methods and procedures to confirm continuing appropriateness in view of advances in technology, updates to Standards, changes in regulations etc.,
- audit and assessment of inspection records and reports/certificates, to confirm consistency and validity,
- witnessing of activities to confirm continuing competence including reassessment of key technical personnel or signatories as applicable,
- audit of quality management system functions to confirm effectiveness of implementation,
- review of facilities and equipment, where applicable, to confirm suitability and effective management.

3.7.1 Routine reassessment

Except where varied by scheme rules, e.g. regulatory requirements, IANZ operates a four yearly accreditation cycle, which requires a Routine Reassessment (RR) visit every fourth year. RRs become due on the anniversary of the initial assessment leading to accreditation (not the date of accreditation). Accreditation does not expire on the anniversary of granting. This allows some flexibility in the timing of RRs, up to a maximum of three months either side of the due date. Continuation of accreditation must be formally confirmed every four years following a satisfactory RR.

Routine Reassessments are similar to initial assessments in their scope, duration, activities to be witnessed and locations to be visited. However the Professional Advisory Committee review process does not apply unless there is a significant change to the scope or to the organisation. Assessment teams for RRs include sufficient specialist expertise to fully assess all technical aspects of the inspection body's accredited activities. Reporting procedures also resemble those at initial assessments.

Essential elements of a Routine Reassessment include;

- full review of system documentation,
- full review of technical documentation,
- reassessment of existing IANZ approved signatories or a sample of inspection body approved signatories,
- observation of inspections and other activities,
- audit of quality system records
- audit of technical records,
- examination of facilities and equipment.

If requested the following activities may also be undertaken during a Routine Reassessment;

- extension of scope of accreditation,
- extension of IANZ approved signatory scopes, where relevant,

- assessment of new signatories for IANZ approval, where relevant.

There are a number of circumstances that may increase the frequency of assessment, these include but are not limited to;

- regulations which impose more rigorous assessment regimes on inspection bodies performing inspections governed by the regulations,
- on-going poor performance during IANZ assessments or tardiness in satisfactorily addressing corrective actions raised during assessments,
- complaints about the performance of an accredited inspection body from any source.

3.7.2 Surveillance assessments

The primary focus of surveillance assessments is to gather sufficient evidence to provide confidence in the effectiveness of the inspection body's systems, to monitor the organisation's accredited activities, to identify any issues that could adversely affect inspection results or compliance with the conditions of accreditation and to respond to these issues appropriately.

In most cases surveillance assessments will be undertaken by an IANZ Lead Assessor alone. Technical assessment will therefore be limited to those aspects in which the Lead Assessor has personal knowledge or expertise.

For the first two years, following initial assessment, surveillance will include a minimum of one on-site surveillance assessment each year to establish confidence in the inspection body's ability to consistently and effectively operate systems required by accreditation.

In accordance with international standards a minimum of one on-site assessment must take place between three yearly assessments.

In preparation for surveillance assessments IANZ may request documents and/or records from the inspection body. Surveillance assessments may include any of the basic elements of assessments. As during initial assessments, evidence may be gathered by the auditing of quality system records, by reviewing inspection records, reports and certificates, by observing activities, examining equipment and facilities, and by speaking to inspection body personnel.

3.7.2.1 On-site surveillance assessment

On-site surveillance assessments take place at the accredited inspection body's premises or location from which inspection activities take place. This need not be an office. If an inspection body has a number of locations, separate from the head office, IANZ will determine which locations are to be visited, based on the scope of work at each location, historical performance and the period since each location was last visited. Each site, at which critical activities take place, must be visited at least once every 4 years.

Whether or not a site visit is needed to a particular office in a given year will be decided by IANZ, based on the performance and circumstances of the inspection body. Factors which may indicate the need for a site visit, include but are not limited to;

- change of premises,
- loss of signatories or other key staff,
- non-compliances identified in previous assessments,
- complaints about the inspection body's performance,
- unacceptable quality of timeliness of responses to requests for information.

IANZ may choose to visit any location from which inspection work takes place, whether critical activities take place there or not.

3.7.2.2 Remote surveillance assessment

When an accredited inspection body has established a good track record of consistent performance in compliance with accreditation requirements, IANZ may consider replacing one of the scheduled on-site surveillance visits in the accreditation cycle with a remote surveillance assessment.

Remote surveillance assessments gather evidence of on-going compliance with ISO/IEC 17020 and the organisation's own quality management systems without travelling to the organisation's premises. Remote surveillance begins with a request for documents and/or records to be provided electronically or in hard-copy. IANZ may request any information for remote surveillance that could be requested during an on-site surveillance visit however the main items are likely to be records of internal audits, management review, competence assessment and training, equipment management, complaints and corrective actions together with some representative samples of inspection records/reports/certificates. Material provided in response to this request is reviewed and a brief report produced. The report lists the information provided and conclusions drawn from it. If corrective actions are considered necessary as a result of the review they will be included in the report.

If all the information requested is not provided within the requested timeframe or if the information provided gives significant cause for concern, IANZ may reconsider the decision to conduct a remote surveillance assessment, in which case an on-site surveillance visit will take place.

3.7.2.3 Activities not included in surveillance assessments

The following activities cannot be undertaken during a standard surveillance assessment;

- review of technical documentation,
- reassessment of existing signatories,
- extension of scope of accreditation,
- extension of signatory scopes,
- assessment of new signatories.

3.7.2.4 Frequency of surveillance assessments

If IANZ has reason to suspect that an inspection body is not consistently meeting the requirements of accreditation, surveillance activity will be increased in frequency and/or extent until confidence is restored.

4 Approval and Endorsement of Inspection Reports and Certificates

Section 5.1 and Appendix 1 of *Procedures and Conditions for Accreditation* (AS 1) sets out the general rules for the endorsement of conformity assessment reports and certificates, and/or the references to accreditation by accredited organisations.

To provide assurance to recipients of inspection results, IANZ allows accredited inspection bodies to endorse inspection reports and certificates with the IANZ name and/or symbol. Approved individuals within the inspection body, personally certify that specific inspections have been carried out in full compliance with the requirements of accreditation. Only when an approved person is prepared to certify that the standards have been fully met can the endorsement be added to a report or certificate.

4.1 Approval of inspection reports and certificates

ISO/IEC 17020 requires all reports and certificates to be approved by authorised staff members. The IANZ Inspection Body Accreditation Programme allows for at least two methods of approving staff to authorise reports and certificates.

1. IANZ approved signatories

Individuals nominated by the inspection body and personally assessed and approved by IANZ during the accreditation assessment process.

2. Inspection body approved signatories

Individuals nominated and formally authorised by the inspection body to supervise and take responsibility for accredited inspections performed by themselves or others. (A sample of these people will be assessed by IANZ to confirm the effectiveness of the process in identifying and authorising competent persons).

In each field or sector of the IANZ Inspection Body Accreditation Programme, one of the above methods will be selected as an application of the ISO/IEC 17020 requirement. The most appropriate method for each field will be determined based on input from the sector, relevant regulators and IANZ. Inspection bodies in a particular field of inspection are generally required to conform to the same model of approval of reports and certificates.

In cases where accreditation is mandated by regulations the choice of model for personnel authorising the release of reports/certificates may be restricted.

Further information on the IANZ Approved Signatory model, and the Competency Model, can be found in Appendix 1. Information regarding the assessment of IANZ Approved Signatories can be found in Appendix 2.

4.2 Endorsement of Inspections

'IANZ endorsement' is a statement by the accredited organisation that the endorsed inspections were performed and reported in full compliance with the requirements of accreditation as specified in the organisation's documented quality management system, accreditation standard and other normative documents (e.g. regulations). Accredited inspection bodies may endorse reports, certificates and other documents containing the results of inspection as long as they meet the criteria for accreditation.

It is the accredited inspection body's responsibility to ensure that the requirements of accreditation and the rules for endorsement have been fully complied with.

In addition to the Rules for the Endorsement of Reports and References to Accreditation set out in Appendix 1 of *Procedures and Conditions for Accreditation* (AS 1), the accredited inspection body must ensure the following:

- (a) All endorsed inspections must have been performed by or have been effectively supervised by an authorising signatory;
- (b) An endorsed report must carry (with their approval) the signature, facsimile signature or printed name of an authorising signatory from the organisation;

- (c) If the authorising signatory is not the person who carried out or supervised the endorsed inspection work then they are responsible for ensuring that rule (a) above was complied with for all work covered by the endorsement;
- (d) If an endorsed document does not carry the hand written signature of the authorising signatory there must be an auditable record of authorisation of the document in the form of a signature, secure electronic release or other secure means.

4.3 Inspection labels on inspected items

Accredited inspection bodies may attach inspection labels to the specified inspected item, and these labels may include the Accredited Inspection Body symbol (IANZ endorsement). Such labels can only be attached where the inspection has been conducted under the inspection body's scope of IANZ accreditation, and shall not give the impression that IANZ approved or inspected the item. Inspection labels carrying the Accredited Inspection Body symbol shall include (as a minimum):

- (i) The name of the accredited inspection body;
- (ii) The inspected item identification;
- (iii) The date of the inspection;
- (iv) Cross reference to the IANZ-endorsed inspection report issued in respect of the inspection.

Appendix 1: Key Staff and Approved Signatories

Key staff

Staff responsible for inspections must have sufficient knowledge and practical experience to enable them to foresee, to recognise and to respond appropriately to any technical or quality system problem likely to arise in the course of the work of the inspection body. Key staff include the Quality Manager, the Technical Manager and the inspection supervisory staff. In some circumstances all inspection personnel may be considered to be key staff and need to be approved signatories.

The qualifications, training, technical knowledge, skills and experience required of inspection body personnel cannot be rigidly specified but must be appropriate to the work in which they are engaged. As a guide, senior staff members would normally be expected to hold tertiary qualifications in a relevant discipline although this is not a requirement. In general, IANZ requires qualifications, training, technical knowledge, skills and experience that correspond to “industry best practice”. Where qualifications are specified in regulations or published Standards these will be pre-requisites for IANZ signatory approval. The ratio of qualified and experienced personnel to other inspection body personnel must be such as to ensure adequate control over the work of the latter. IANZ recognises certain staff members as having special responsibilities and these are called approved signatories.

Approved signatories

ISO/IEC 17020:2012 clause 7.4.2 requires all inspection reports/certificates to be approved for release by authorised personnel. The persons authorised to approve endorsed reports/certificates for release are known as approved signatories.

Approved signatories are staff members, nominated by the inspection body after achieving an appropriate level of knowledge, skill, understanding, experience and professional judgement in accordance with the inspection body's training and competence system. Traditionally all signatories nominated by an inspection body were also assessed by IANZ and, if successful, have been designated as “IANZ approved signatories” and have been listed in schedules to certificates of accreditation. In some circumstances larger inspection bodies (more than 5 inspectors) may be considered for a different approach in which signatories are nominated and approved by the inspection body and IANZ will witness and assess a sample of these signatories as a means of assessing the effectiveness of the inspection body's systems for approving signatories.

Signatories, however appointed, are the only persons authorised to release reports, certificates or other documents which report on inspection activities and which claim accredited status, usually by carrying an IANZ endorsement. In all cases the inspection body's procedure for nominating signatories must include a requirement to demonstrate an understanding of accreditation, and the duties and responsibilities involved in authorising the use of the IANZ symbol.

Note: In fields where accreditation to ISO/IEC 17020 is a requirement of regulations, Standards or other scheme rules all reports/certificates are considered to be ‘endorsed’ whether they carry an explicit endorsement or not and therefore they must be subject to the rules and procedures relevant to IANZ endorsed reports/certificates and are legitimate subjects of IANZ assessment team scrutiny.

An inspection body may have any number of approved signatories and it is not a requirement that any single signatory be approved for the entire scope. However, the scope of accreditation of the organisation is automatically limited to the sum of the scopes of its approved signatories. It follows that the scope of an accredited inspection body is automatically reduced if the only signatory approved for a specific activity is no longer available to the organisation. It also follows that accreditation automatically becomes inoperative (suspended) if an inspection body loses all its approved signatories. There is a clear vulnerability for organisations choosing to have a single signatory for each type of inspection.

Signatory approval is not a transferable personal qualification as it is linked to a specific management system. It lapses when a person ceases to be employed or contracted by that inspection body.

Assessment models

Depending on the requirements of the specific sector of which the inspection body is part, including any regulatory or legal requirements, and any sector-wide decisions, IANZ may choose one of two main types of models for assessment of inspection personnel.

IANZ Approved Signatory model

This model requires staff to be individually approved by IANZ as Signatories before they are able to endorse inspection reports and certificates for their IANZ approved scope. Some industry regulators require inspection bodies to apply the Signatory Model.

Competency model

This model involves sampling of a selection of staff and locations (if appropriate) to establish whether the inspection body's system for establishing competence and authorising of staff is working appropriately. In practical terms, for small inspection bodies the number of Inspectors observed is the same when applying either the IANZ approved Signatory or Competency Model.

To decide how many inspectors are to be observed using this model, IANZ will develop a framework of types of inspections to be observed for each industry group to ensure all types and levels of skills are observed. This will be determined by IANZ in consultation with relevant technical specialists and when appropriate, relevant regulators.

If the assessments determine that the inspection body's system for establishing competence and authorising of staff is working appropriately for a type of inspection, all inspectors authorised by the organisation as signatories are able to endorse inspection reports and certificates for that type of inspection.

If one or more witnessed individuals are considered, by the assessment team, to have significantly different competency levels to those recorded by the inspection body the inference may be drawn that the inspection body's systems for establishing competence are not effective. The assessment team may make a decision that more witnessing is required than originally planned. This could require extending the assessment time or, in serious cases such a finding could result in that part of the scope not being awarded or the suspension of all or part of an inspection body's accredited scope (if already accredited).

Signatory requirements

As signatories are responsible for the validity and reliability of the reports and certificates they authorise for release, they must be in a position to confirm that the work they release has been completed competently and in full conformance with the requirements of accreditation. It is the responsibility of the inspection body to design and operate systems to ensure the required level of confidence in inspection reports/certificates.

Where inspectors work in teams or with close supervision it may be appropriate for only the supervisor(s) to be the signatories. A signatory must be available to give guidance or take decisions whenever accredited inspections take place and to be able to perform whatever confirmatory checks they consider necessary before releasing reports/certificates. These may include site visits in some circumstances. This requirement should be taken into consideration by inspection bodies when making proposals to IANZ regarding the number of signatories required and their geographical distribution.

In situations where inspectors routinely carry out inspections without close supervision and remote from technical support, it is advisable for each inspector to be an approved signatory.

Signatory approval is available to contracted personnel, as well as part-time or full time employees, provided there is a written agreement between the parties setting out the extent of the authority and responsibility of the individual in relation to the inspection body. If a contracted signatory is to be in a supervisory position their position in relation to the inspection body must be such that they can perform their role as supervisors as effectively as if they were full time employees.

Signatory responsibilities

Signatories are approved for a specified technical scope and may only authorise the release of work within that scope. An exception to this limitation is where a signatory authorises the release of a report, certificate or other document which is a compilation of work, each item of which has been authorised for release by an appropriately approved signatory.

The authorising signatory is personally responsible for the compliance of the endorsed work with the requirements of accreditation as defined in the inspection body's documented systems and relevant normative documents.

Before authorising the release of an endorsed document, the signatory must be satisfied that all accreditation requirements have been met.

If the document includes contributions from persons in the accredited inspection body that are not approved signatories, it is the signatory's responsibility to ensure that the necessary supervision and checks of the work have been carried out either by themselves or another named approved signatory in the organisation.

Appendix 2: Signatory Assessment

Aim of the process

The purpose of signatory assessment is to establish the personal competence of an individual to perform specified tasks as documented in their inspection body's quality management system.

The task of the assessment team is to decide on an appropriate scope of approval for the applicant. Decisions are based on documents provided in advance and the performance of the individual during the assessment.

Wise applicants take full advantage of this opportunity to demonstrate their technical skills and knowledge and familiarity with their organisation's systems.

Applicants should ensure that documentary evidence such as work history and training records accurately reflects their experience, knowledge and current skills.

Briefing the assessment team

In order to undertake a thorough assessment of an individual, the assessment team need to be familiar with a range of relevant material. Information normally requested prior to the assessment would include:

- relevant quality system documentation including technical procedures and work instructions,
- an application for signatory approval which includes the requested scope or a statement of the scope for which the inspection body considers the individual to be suitable as a signatory,
- current training records including current assessed competence in each activity or procedure,
- details of the inspections to be witnessed. The level of detail required will depend on the field of inspection. An indication of the general types of inspection to be observed may be sufficient in some cases. In others the team may require extensive documentation on the specific inspections. Specific requirements will be made clear during the pre-assessment meeting,
- details of any personal protective equipment or induction training needed by the assessment team.

The inspections to be observed should whenever possible be real inspections rather than demonstrations for the purpose of the assessment.

An assessment will be successful when the individual is able to demonstrate the following to the satisfaction of the assessment team:

Technical/specialist skills:

- appropriate qualifications
- relevant current experience
- close day-to-day technical involvement in inspections
- technical/specialist knowledge of the items inspected
- responsibility for inspection decisions
- sufficient length of service with the inspection body (normally at least six months)
- competence in the inspection activity for which approval is sought
- practical ability to perform a credible inspection and to record observations
- an in depth appreciation of the limitations of the inspection procedures
- an understanding of the relevant technical/specialist details of the items inspected
- an awareness of the types of non-conformances likely to be found
- the ability to identify non-conformances
- an understanding of the significance of observations
- a sound judgement in evaluation of findings.

Other skills:

- an understanding of quality system principles
- a working understanding of the requirements of accreditation
- a good working knowledge of the inspection body's documented quality system and procedures (not just the technical procedure they are asked to demonstrate.)
- a working knowledge of ISO/IEC 17020 and IANZ documents
- a clear understanding of signatory duties, responsibilities and limitations
- a clear understanding of IANZ rules including those for endorsement.

If an applicant is working in an organisation which is fully compliant with the requirements of accreditation they should not need to do any special preparation for the assessment.

Briefing the personnel to be witnessed

The following issues will normally be reiterated to individuals immediately before they start a witnessed activity:

- Once the witnessing commences the inspector is in charge and should undertake the activity as they normally would do,
- The assessment team will take a largely passive role, watching the whole process. The assessment team will assume that what they see is typical of the individual's normal work,
- If for whatever reason the person being witnessed decides not to do something they would normally do they should explain this to the assessors,
- It is good practice for the witnessed person to speak to the assessors from time to time to give an insight into their thought processes (what they are looking for and why),
- It is bad practice for the witnessed person to substitute describing the activity for doing the activity,
- Assessors will not prompt or lead the inspection in any way except where a professional duty of care makes intervention imperative,
- When the witnessed person is satisfied that the activity is completed assessors may ask questions or enter into a discussion with the witnessed person. The aim of such questions or discussions is to allow the witnessed person to demonstrate competence or clarify issues that may not have been clear to the assessors during the witnessed activity.

Appendix 3: Multi-site Accreditation

Organisation

For the purpose of accreditation an organisation is a legal entity or identifiable part of a larger legal entity, which operates under a single documented quality management system including all specialist systems and procedures.

Branches

A branch is any part of an accredited organisation, which has one or more of the following features:

- authority to accept new work independently of the main branch,
- authority to formulate policy, procedures or methods independently of main branch,
- independently maintains copies of quality system documents,
- operates under the same quality management system as all other branch,
- holds copies of records and/or reports which are not duplicated at main branch,
- has fixed facilities or equipment which are critical to inspections.

Multi-site accreditation

For organisations with a number of branches all using the one quality management system one “branch” is normally designated as the main branch (or head office). The main branch will be assessed annually. Other branches will be assessed initially and then at least once during the accreditation cycle.

If a location owned by an organisation operates a management system significantly different from that of the main branch it will require a separate accreditation.

An organisation composed of a head office and one branch would be treated as an organisation with two branches for the purpose of accreditation.

Satellite sites

Offices/places of work from which work is carried out and which the inspection body requires to be listed on their scope of accreditation but do not meet the requirements of a “branch” as defined above will be determined to be a “satellite office” for the purpose of annual fee requirements.

Assessment fees

Fees for multi-site accreditations will reflect the lesser cost to IANZ of maintaining one accreditation. All fees are at the inspection body's expense at rates published in the current IANZ fee schedule.

Main sites will be charged two standard unit fees and branch offices will be charged 0.5 unit fees. Satellite sites will be charged 0.05 unit fees. One accreditation international recognition levy will be charged per accreditation.

Appendix 4: Scopes of Accreditation

Overview

Detailing the scope of an organisation's accredited inspection activities is one of the distinguishing requirements of accreditation. To do this it is necessary to specify the types of designs, products, services, processes or plant that are inspected; the stages at which inspections may take place; the regulations, standards or other specifications against which conformity is assessed and for which accreditation may be granted.

Competence resides in people not systems or equipment. It is therefore essential that an inspection body clearly defines the competencies required for each scope item and has systems to identify the individuals with the competencies required for each scope item. An inspection body cannot gain or retain accreditation for any scope item unless at least one person in the organisation can demonstrate the required competence for that activity.

Accreditation is normally granted only for work that is performed regularly and for which organisations are properly equipped and have demonstrated their competence. Accreditation may be granted for inspections that are performed rarely, provided the inspection body has documented procedures to maintain and update the necessary knowledge and skills and can demonstrate their effectiveness.

Purpose of scopes

Scopes are used by many parties and for many purposes. The following summarises these:

- Applicant Inspection bodies draft a scope to define what they wish to be accredited.
- Accredited inspection bodies use scopes to define which activities are accredited.
- Accredited organisations and IANZ use scopes to define who, within the inspection body, can authorise the release of endorsed reports/certificates etc. for each type of work.
- Accredited inspection bodies use scopes as publicity for their services.
- IANZ uses scopes to assemble appropriate expertise for assessment teams.
- IANZ and accredited inspection bodies use scopes to limit the scope and reach of assessments.
- IANZ creates scopes to comply with relevant international standards.
- Regulators use scopes to gain confidence that organisations are accredited for regulatory purposes.
- Clients of inspection bodies use scopes to find appropriately accredited inspection service providers.

To meet all of these needs the following technical information must be included in scopes where relevant.

- industry sector e.g. Engineering, Food and Agriculture, Building, etc.,
- types of designs, products, services, processes or installations that are inspected e.g. food control plans, cranes, pipelines, fire sprinklers etc.,
- inspection methods used e.g. published industry standard methods, regulatory specifications, specified in-house methods, customer defined methods, etc.,
- life cycle stage at which item is inspected e.g. design, fabrication, growth, harvest, production, in-service, modification/repair etc. (terminology varies with industry sectors),
- independence category in accordance with ISO/IEC 17020 parameters.
- specifications against which conformance is determined e.g. Standards, Codes of Practice, Regulations, etc.

IANZ publishes scopes on its website in the form of a Schedule to the Certificate of Accreditation. The schedule includes all of the technical information listed above and additional information such as contact details, accreditation numbers and dates etc. This information is publicly available.

It is important for all concerned that scopes are expressed clearly, unambiguously and consistently. To achieve this IANZ has compiled a list of currently accredited inspection activities from which scope wording is selected.

Extension of scope

Extensions of scope may be requested at any time. The level of assessment required for an extension of scope will depend on the nature of the requested extension and its relationship to the existing scope and the demonstrated competencies of the inspection body's specialist personnel. The level of assessment required is determined by IANZ and ranges from a desktop review to a full on-site assessment with one or more technical experts.

Extensions of scope will not be granted, other than in exceptional circumstances, until any corrective actions have been formally cleared and then only if the corrective actions are not related to the requested extension.

As with all initial assessments of competence, if any CARs, raised during assessment for an extension of scope remain un-cleared more than one year later, an additional assessment will be needed before the extension can be granted.

Reductions of scope

A reduction of scope may be affected by a detailed written request, which will be actioned and confirmed by the issue of an amended Schedule to the Certificate of Accreditation.

A reduction of scope may also take place automatically due to circumstances such as the loss of a key member of staff or the temporary or permanent loss of a critical piece of equipment required for a specific type of accredited work. If an accredited inspection body cannot meet the requirements of accreditation for whatever reason, they must not issue endorsed reports or certificates, for the types of inspection affected, whether IANZ has been informed or not.

Failure to inform IANZ of circumstances that could significantly affect the scope of accreditation may result in a special assessment, a requirement to recall reports/certificates and/or full or partial suspension or withdrawal of accreditation. Making any claim or suggestion that an organisation is accredited for specific work for which it is not currently accredited is also an offence under the Act.

Appendix 5: Assessment Sampling

Assessment planning

When planning an assessment, IANZ will establish the need for sampling where the scope of accreditation of the inspection body covers a variety of sites/signatories/scope items.

For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the inspection body from which one or more key activities are performed or where records of key activities are maintained and which are covered by the scope of accreditation.

Note: Key activities may include but are not limited to:

- *Policy formulation,*
- *Process and/or procedure development,*
- *Initial selection of inspectors and planning inspections,*
- *Taking on new work (contract review) independent of the head office,*
- *Review, approval and/or decisions on the results of inspections,*
- *Maintaining of records and management system documentation not otherwise kept at the head office,*
- *Equipment maintenance and calibration,*
- *Management of critical consumables.*

In establishing the levels of assessment required a number of factors are taken into consideration including:

- number of branches,
- number of inspectors,
- number of signatories,
- extent of signatory scopes,
- diversity and complexity of inspections,
- rate of change in each field in the scope (science/technology, Standards, regulations, specifications etc.).

Surveillance and reassessments will be planned to ensure the following items are fully covered over the assessment cycle (generally three years):

- Scope of accreditation - Each scope item (or group of similar items) must be assessed at least once during the assessment cycle.
- Signatories – Each IANZ approved signatory must be assessed at least once during the assessment cycle.
- A selection of personnel and their levels of experience/training.
- All branches/locations at/from which key inspection activities occur.

IANZ will record its sampling decisions and the rationale behind those decisions for each client.

Appendix 6: Equipment Calibration and Traceability

Calibration requirements

ISO/IEC 17020:2012 clause 6.2.6 states that where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme.

The inspection body's calibration programme shall ensure that measurements made by an inspection body are traceable to a national or international standard of measurement, where appropriate.

It is preferred that calibrations are performed by a national meteorology institute or an accredited calibration laboratory whose services are suitable for the intended need (i.e. the scope of their accreditation specifically covers the appropriate calibration). More detail regarding the meaning of the term 'measurement traceability' is available in ILAC P10 which is available free of charge from IANZ on request.

Calibration of measuring equipment by non-accredited organisations

If for any justifiable reason, it is not possible to have equipment externally calibrated by an accredited calibration laboratory, then, with the agreement of IANZ, inspection bodies may have calibrations performed by a non-accredited calibration laboratory or carry out calibrations and commissioning checks on their own test and measuring equipment, providing they are equipped to do so, have acceptable written methods, can demonstrate the required expertise and they are performed in accordance with the relevant criteria for metrological traceability as defined in ISO/IEC 17025.

Inspection bodies that are approved to carry out calibrations and commissioning checks on their own equipment do not have this activity included in their scope of inspection body accreditation and are therefore not accredited to calibrate equipment for other organisations.

Case for not calibrating measuring equipment

Under certain circumstances, clause 6.2.6 enables an inspection body to make a case for not calibrating equipment even if the measurement makes a significant contribution to conformity decisions. Specialist assessors and IANZ lead assessors will consider any logically reasoned argument for it not being 'appropriate' for a particular measuring instrument to be calibrated. However, to be acceptable the case must be made on technical grounds rather than cost or inconvenience. The justification for not calibrating equipment that has a significant influence on the outcome of an inspection must be documented to enable a technical expert to assess the rationale for the decision and to provide institutional memory for the inspection body.