



Procedures and
Conditions of
Accreditation



Procedures and Conditions of Accreditation

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general criteria for accreditation

Procedures and Conditions of Accreditation

AS 1

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Published by:
International Accreditation New Zealand
626 Great South Road, Ellerslie, Auckland 1051
Private Bag 28908, Remuera, Auckland 1541, New Zealand
Telephone 64 9 525 6655
Facsimile 64 9 525 2266
Email: info@ianz.govt.nz
Internet: www.ianz.govt.nz

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Scope

Procedures and Conditions of Accreditation (PCA) explains the structure of International Accreditation New Zealand (IANZ) and the procedures for accreditation by IANZ in the following IANZ accreditation programmes:

- Laboratory accreditation
- Radiology Services accreditation
- Reference Material Producers accreditation
- Proficiency Testing Providers accreditation

Similar publications are available for the IANZ Inspection Body accreditation programme and the IANZ Building Consent Authority accreditation programme and are specific to those respective programmes:

- *Procedures and Conditions of Inspection Body Accreditation* (AS 3)
- *Procedures and Conditions of Building Consent Authority Accreditation* (AS 4)

After briefly introducing IANZ, Section A of this document overviews the accreditation programmes before discussing accreditation procedures in detail. Section B describes the rights and duties of accredited organisations.

This version of PCA supersedes the sixth edition published in October 2015.

Section A: Accreditation Procedures

1 Introduction

IANZ is a national technical accreditation body, a multi-disciplinary agency with internationally recognised expertise in accreditation programme management.

Accreditation is the formal recognition of technical competence through assessment of an organisation's management system (both quality and technical systems), involving a detailed on-site assessment of the organisation's competence in key technical areas such as staff, methods, equipment, accommodation and the like. Assessment teams normally consist of one IANZ Lead Assessor and at least one technical expert to evaluate the technical system. Larger teams are used in bigger organisations or those seeking more extensive accreditation.

Accreditation provides formal recognition that an organisation is meeting internationally accepted standards of quality, performance, technical expertise and competence. Accreditation is an independent endorsement of an organisation's commitment to these standards.

IANZ operates accreditation programmes for the following:

- Laboratories;
- Inspection Bodies;
- Radiology Services;
- Proficiency Testing Providers;
- Reference Material Producers;
- Building Consent Authorities.

The accreditation of Inspection Bodies and Building Consent Authorities is outside the scope of this document.

IANZ also registers:

- Test facilities meeting the OECD Principles of Good Laboratory Practice. The registration of these facilities is not within the scope of this document – see *Procedures and Conditions of GLP Registration* (AS 2);
- Conformity Assessment Bodies designated for Government to Government trade agreements.

Laboratory and Inspection Body accreditations are offered in a number of fields of technology. Similarly, Radiology Service accreditation covers a number of different diagnostic imaging disciplines. Details of these are available from IANZ.

Laboratory accreditation is offered by IANZ to both testing and calibration laboratories.

2 Structure

Initially established by Act of Parliament in 1972 (as the Testing Laboratory Registration Council), the Accreditation Council is IANZ's governing body and is a statutory body now established under and operating in accordance with the Standards and Accreditation Act 2015. The Council is a not-for-profit, user-funded Crown entity that promotes the highest possible technical standards in New Zealand's industrial, technical, commercial, regulatory, health care and administrative sectors.

The Act establishes a Council of five to seven members who are responsible to the Minister of Commerce for the administration of its programmes. The Council works very much as a board of directors, responsible for the broad strategic management of IANZ activities. Day to day supervision is delegated to the Council's Director, the Chief Executive of IANZ.

The General Manager - Accreditation Services, Programme Managers and Accreditation Assessors hold appropriate qualifications in science, engineering and technology and are experienced in management system operation and assessment.

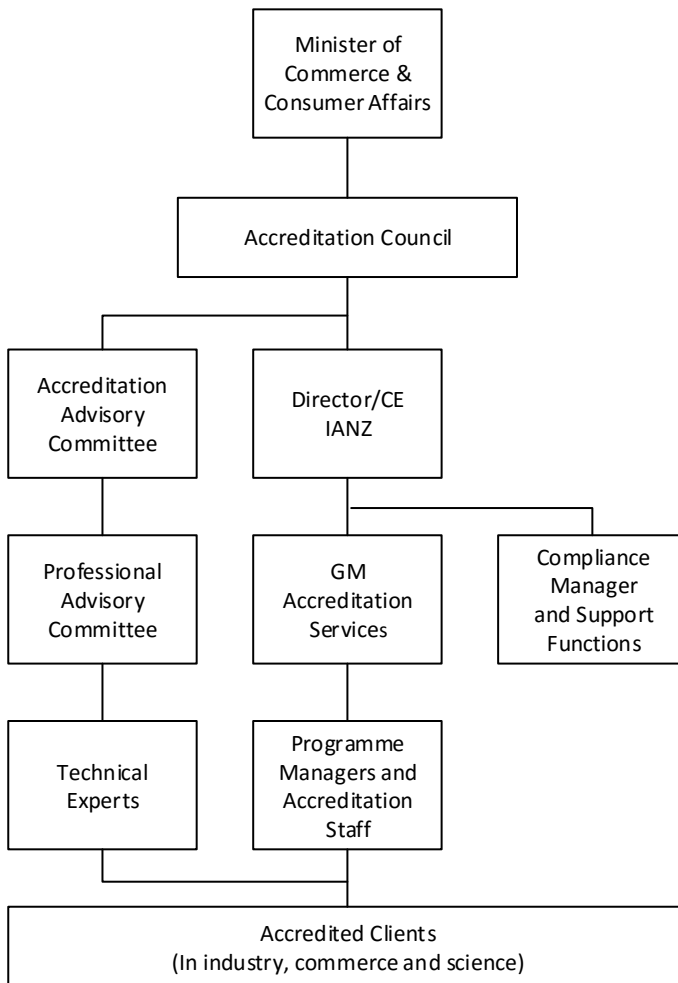
The Accreditation Advisory Committee (AAC) is a Council-appointed committee of experts assisting IANZ in the operation of the accreditation programmes. Its functions are:

- (a) To provide technical advice on accreditation policy matters to the Council as required;
- (b) To provide IANZ and the Council with liaison and feedback from the New Zealand and international technical and accreditation community;
- (c) To review with the IANZ secretariat, the generic criteria for accreditation to be applied across all fields of technology, as well as maintain some consistency throughout field specific criteria documents for accreditation;
- (d) To review with the IANZ secretariat, national and international developments in professional body accreditation;
- (e) To function as an independent expert body which can be consulted by the Council for adjudication on any appeals arising from IANZ's accreditation activities;
- (f) To assist the General Manager - Accreditation Services, where required, in the establishment of ad hoc professional advisory committees in response to particular technical questions;
- (g) The Chairperson shall recommend (to the Chief Executive of IANZ, under delegated authority from the Council) the granting of accreditation to applicant organisations following the review and a positive recommendation the relevant Professional Advisory Committee.

Technical advice and review of the accreditation programmes are also provided by Professional Advisory Committees (PAC) for each broad area of technology. Key PAC functions are similar to those of the AAC, but also include:

- (a) Technical review of assessment reports and responses from applicants for accreditation;
- (b) Approval of specific criteria documents;
- (c) Review of technical experts;
- (d) Providing general technical advice in the area of technology concerned.

2.1 Organisation Chart



3 Operational Standards

3.1 IANZ Operational Standards

The operation of the IANZ Laboratory, Radiology Service, Proficiency Testing Provider and Reference Material Producer programmes complies with the requirements of the international standard ISO/IEC 17011: *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*.

IANZ accreditation programmes are subject to regular internal audit, as well as external evaluation by overseas accreditation co-operations with which IANZ has mutual recognition arrangements. This ensures compliance with these standards.

3.2 Accreditation Standards (General Criteria)

Accredited organisations are assessed against all of the requirements of the following standards:

Note: these standards may be New Zealand adoptions and will have NZS in the standard title but are otherwise unaltered.

Laboratories (except Medical Testing)

ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*.

Laboratories (Medical Testing)

ISO 15189: *Medical Laboratories - Requirements for quality and competence*.

Radiology Services

The *New Zealand Code of Radiology Management Practice*, developed from ISO 15189, modified specifically for radiology services.

Proficiency Testing Providers

ISO/IEC 17043: *Conformity assessment – General requirements for proficiency testing*.

Reference Material Producers

ISO 17034: *General requirements for the competence of reference material producers*.

3.3 Technical Criteria

In addition to the general requirements of the accreditation standards in 3.2, organisations are also assessed and accredited against more specific technical requirements relating to international requirements established under the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) of which IANZ is a member, and accepted good practice for that particular scientific discipline or technology. Where needed these are defined in IANZ Technical Policy documents and, along with the IANZ requirements for approved signatories or key technical personnel as relevant to the particular programme, in IANZ Specific and Supplementary Criteria documents. Approved signatories / key technical personnel are staff members recognised by IANZ as competent to release results and/or authorise reports and other information and are an integral part of some IANZ accreditation programmes.

(a) Technical Policy documents

IANZ Technical Policies contain generic technical criteria for accreditation that apply across multiple IANZ accreditation programmes. They generally reflect internationally agreed interpretations or applications of specific technical requirements contained in the accreditation standards. Examples include IANZ policies for traceability of measurement and for participation in proficiency testing activities.

(b) Specific Criteria for Accreditation

These contain technical and/or administrative criteria relevant to a specific accreditation programme and/or technical area of activity. For example, each field of testing in the laboratory accreditation programme has a Specific Criteria for Accreditation publication which outline particular requirements relevant to that type of testing.

(c) Supplementary Criteria for Accreditation

Where needed, Supplementary Criteria for Accreditation may be published to support the Specific Criteria, and are general more focussed on particular sectors, activities and or sub-programmes.

4 Accreditation Procedures

4.1 Overview

Organisations seeking accreditation by IANZ will need to document their technical and quality systems in a manual (or other alternative set of procedures). These procedures have to meet the requirements of the relevant standard for their type of activity in Section 3.2. A schematic overview of the accreditation procedure is shown in the flowchart in Section 4.13.

4.2 Information and Preliminary Discussions

Information about IANZ accreditation programmes is freely available on the IANZ website at www.ianz.govt.nz or upon request, as are copies of the general (where copyright provisions allow), specific and supplementary criteria relevant to the organisation's activities. In addition, IANZ accreditation staff members are available for advice and assistance.

Organisations may request an advisory visit to their premises by an IANZ staff member to review their existing systems and procedures and/or to explain accreditation in more detail. This service is provided at the IANZ normal hourly professional fee plus expenses. IANZ can advise on the readiness for the initial assessment and, also, on any aspects of the management systems that need further development. However, IANZ cannot provide detailed advice or documented procedures that are in the nature of consultation.

If organisations have had no formal contact with IANZ in the past, such a visit is strongly recommended. Experience suggests that the cost of an advisory visit will be more than recovered by the savings in time at the initial assessment.

4.3 Formal Application for Accreditation

Application fees (as detailed in the current issue of the relevant IANZ fee schedule, freely available on the IANZ website at www.ianz.govt.nz or upon request) may either be submitted with the application, or will be invoiced at the time of application acknowledgement.

Before the initial assessment, it is essential that enough background information is provided to IANZ to enable IANZ staff to select appropriate technical expert(s) and to brief them prior to their visit to the applicant organisation. The necessary information is requested in an Accreditation Questionnaire which accompanies the application form and should be returned with it. Some of the important information IANZ needs in the questionnaire is:

- (a) The classes / types of test / service for which accreditation is sought. These are detailed in the IANZ Specific Criteria document for the particular technology and/or activity;
- (b) The staff members the organisation wishes to nominate as IANZ approved signatories or key technical personnel, where relevant;
- (c) The test procedures or other work methods used within each technical area;
- (d) Each site for which accreditation is sought;
- (e) Details on proficiency testing participation and results;
- (f) Other organisation records as requested.

Each application is allocated to the appropriate IANZ Programme Manager (PM) for the field of technology concerned. The PM will designate a Lead Assessor who will review the submitted documentation in detail and contact the applicant organisation to arrange a suitable date for the assessment and to discuss the proposed technical experts. Where practical, all sites offering the services for which accreditation is sought will need to be visited by the assessment team.

4.4 Authorised Representative

Each applicant and each accredited organisation must nominate a senior staff member to represent it in all dealings with IANZ. This person is the IANZ point of contact with the organisation and is known as the Authorised Representative. All correspondence, invoices, etc. which IANZ sends to the organisation will be addressed to the Authorised Representative.

The Authorised Representative may be any senior staff member from either the technical or managerial staff. It is important that they are in a position of sufficient authority to ensure their organisation complies with the criteria for accreditation at all times. There are advantages in nominating a person who is not closely involved in the day-to-day operation but has authority over it.

If an Authorised Representative resigns, or if an organisation wishes to replace that person, then IANZ must be informed as soon as possible of the name of the new Authorised Representative.

The Authorised Representative is expected to be present at on-site assessment entry and exit meetings.

4.5 Documentation Review

Before the on-site assessment of the applicant organisation, relevant manuals and supporting documents making up the technical and quality systems will be comprehensively reviewed to ensure compliance with the relevant general criteria (the standards), the relevant specific criteria and other criteria as detailed in this publication. Prior to or during on-site assessment, the applicant will be notified of any significant changes needed to their documents.

4.6 Approaching the Initial Assessment

IANZ encourages organisations to consider the positive, helpful elements of the assessment and to regard it as an opportunity to obtain professional, technical and quality management advice. The assessment team is not there to find fault. Its function is to provide helpful comment and suggestions to enable you to maintain an effective technical and quality system.

The assessment is a fact-finding exercise undertaken jointly by the organisation's staff and the assessment team.

IANZ maintains a panel of specialised technical experts who are chosen for their personal knowledge and expertise. They are drawn from industry, commercial organisations, research associations, consultancies, academic institutions and government departments, both within New Zealand and overseas. The assessment team comprises the IANZ Lead Assessor and one or more assessors and/or technical experts. When acting on behalf of IANZ, the technical expert does not represent their employer or any other organisation with which they may be associated.

Organisations have the right to veto the use of particular technical experts proposed for any assessment, provided the reasons are valid e.g. conflict of interest.

4.7 The Assessment Procedure

The objective of IANZ assessments is to confirm that organisations are actually doing what their procedures say they will do and that it meets good practice for that discipline. During its on-site visit, the assessment team will focus on the technical operations, the quality system, the competence of personnel (including signatory applicants and key technical personnel as appropriate), and on the methods used. Information gathered will include, but is not limited to, review of records, discussions with management and technical personnel and the observation of activities within the requested scope of accreditation. The team may wish to witness tests or other work relevant to the scope.

Health and Safety at Work Act 2015

Under the Health and Safety at Work Act 2015 and associated Regulations, IANZ, as a 'person conducting a business or undertaking (PCBU)', shares some responsibility with the assessed organisation, also a PCBU, for the health and safety of members of the IANZ assessment team while conducting the assessment of the organisation at their site. IANZ recognises that as the 'host' PCBU, the assessed organisation is in the best position to have identified potential hazards / risks to their workers and thus also the IANZ assessment team, and to design and implement appropriate control measures to minimise any risk. Accordingly, IANZ will request that such information and any associated instruction and/or supervision is formally passed onto all members of the IANZ assessment team prior to, or at the commencement of, the on-site assessment. While at the site, all members of the IANZ assessment team will comply, at all times, with any instructions given.

On some occasions, assessment activities (typically witnessing of accredited activities) may be undertaken at (a) site(s) other than the assessed organisation's own site (e.g. at the site of their client). It is IANZ expectation that the assessed organisation will, as a responsible PCBU, actively seek health and safety information and instruction from the 'host' PCBU at these sites and that this information is also formally passed onto all members of the IANZ assessment team.

IANZ has a duty to record the fact that this information was provided and received by members of the assessment team. Failure to provide this information, on the part of the assessed organisation, to the satisfaction of the Lead Assessor constitutes grounds for delaying or terminating the assessment.

Most assessments take one or two working days to complete but visits to larger organisations, or those whose work extends over a range of technologies, will take longer. The assessment begins with a meeting between the IANZ team and the senior staff of the organisation. This entry meeting provides an opportunity for:

- The timetable and scope of the assessment to be finalised;
- A health and safety briefing for the assessment team;
- A review of the Accreditation Questionnaire;
- Resolution of any immediate queries that the assessors or staff may have.

Organisations are asked to provide a guide(s) / escort(s) for each assessment team member for the duration of the visit. These escorts should be senior staff members of the organisation who have sufficient authority to ensure that assessors have access to all documents, personnel and activities they may wish to see.

Observations made during the assessment will be recorded on a checklist or notebook. These will include observations of compliance as well as of any non-compliance.

Following the information gathering, the assessors meet to review their notes and summarise their findings.

The assessment ends with an exit meeting where representatives of the organisation are provided with summarised findings including details of any areas of non-compliance that have been found and guidance on correcting them. All findings will be fully discussed before the team leaves.

Within ten working days of the visit, the organisation will receive a comprehensive written report on the assessment findings which were discussed at the exit meeting. The report will generally place the findings into two categories: Corrective Action Requests (CARs) and Recommendations. Some accreditation programmes make use of an intermediate classification of Strong Recommendations.

- (a) **CARs** are actions that the organisation must carry out before accreditation can be granted. CARs usually relate to non-compliance with the General or Specific Criteria;
- (b) **Strong Recommendations** (where used) are actions that may represent actual minor nonconformities, or potential nonconformities with accreditation criteria;
- (c) **Recommendations** are actions that the organisation is urged to carry out in the interests of good practice, but are not considered CARs.

The IANZ Lead Assessor will monitor progress in carrying out the required actions. Once the Lead Assessor is satisfied that all conditions for accreditation have been cleared, they will prepare a report on the assessment for consideration by the General Manager - Accreditation Services and the relevant PAC. This includes the proposed scope, the assessment report and responses to it, information on the key personnel, as well as any relevant proficiency activity and follow-up action.

The PAC members review the assessment report. If they are satisfied that all accreditation criteria have been met, they advise the Chairman of the AAC who will recommend to the IANZ Director that accreditation may be awarded on behalf of the Council. The recommendation includes the particular tests or types of activities for which accreditation is to be granted and, where relevant, the names of staff that are to be awarded signatory approval or have been appointed as key technical personnel. A formal offer of accreditation will be issued along with an Acceptance of Accreditation Conditions agreement for signature and return. The annual administration fees will also be issued at this time. On receipt of the signed agreement and payment of fees, the Council will grant accreditation, issue a Certificate of Accreditation and publish the name of the organisation, together with details of its scope of accreditation, on its website at www.ianz.govt.nz.

Accreditation certificates remain the property of IANZ.

Accreditation allows the accredited organisation to endorse relevant certificates, reports or other relevant outputs in the name of IANZ. The detailed requirements for IANZ endorsement are given in Appendix 1 to this publication. Endorsement with the IANZ accreditation symbol is not compulsory (except in the case of calibration laboratories) but is strongly encouraged because it adds credibility to the work of the accredited organisation.

4.8 Continuation of the Initial Assessment

Where major departures from accreditation criteria are found during an initial assessment, a further visit may be needed to confirm the assessment team's requests have been carried out. Where departures are less serious but remain un-cleared for more than one year after the initial assessment, another visit will also be needed for accreditation to proceed.

4.9 Scope of Accreditation

Detailing the scope of an organisation's technical activities is one of the distinguishing requirements of accreditation. To do this it is necessary to specify the range of activities and services that are provided under the control of the organisation's technical and quality systems.

Accreditation is normally granted only for work that is performed regularly and for which organisations are properly equipped and have demonstrated their competence. The scope of accreditation will, therefore, vary with the range and complexity of work carried out, the competence and experience of staff and the level of technology available in the organisation. Should an organisation wish to be accredited for activities rarely carried out, its staff will need some means of keeping up to date with those activities. This can include comparative tests within the organisation or with others, participation in inter-laboratory comparison programmes or regular testing / inspection of retained artefacts.

In granting accreditation IANZ will specify, as appropriate, the following details in the scope of accreditation:

- (a) The activities and services provided;
- (b) Test/activity methods used (e.g. Class 2.06: Chemical tests on cement in accordance with NZS 3122:1995);
- (c) For calibration laboratories, ranges of measurements and least uncertainties (e.g. Class 5.21: Calibration of Masses over the range 50 to 300g to a least uncertainty of 2 parts per million at 95% confidence).

The available activity classes e.g. classes of test, are detailed in each Specific Criteria document for the relevant technologies.

There is currently a Specific Criteria booklet available for each field of testing in the Laboratory Programme. Activity classes may relate to products, services and/or equipment.

Organisations may carry out calibrations and commissioning checks on their own test and measuring equipment providing they are equipped to do so, have acceptable written methods and the required expertise. Such internal calibrations conducted for other organisations will not be accepted by IANZ unless specific accreditation for these activities has been granted.

4.10 Surveillance and Reassessment

Once accredited, organisations enter the IANZ programme of scheduled reassessment visits. These visits ensure that the technical and quality systems continue to meet the criteria for accreditation and continue to work effectively. IANZ reserves the right, however, to undertake an extra reassessment at any time should evidence suggest that this may be necessary.

Full technical (routine) reassessments are usually carried out at three yearly intervals, although for medical testing laboratories and radiology services intervals may be up to four years and some special accreditation programmes require annual or more frequent reassessments.

Full technical reassessments are similar to initial assessments in their scope, duration, and process. Reporting procedures also resemble those at initial assessments, but once accredited there is a limit on the time organisations may take to carry out any requested changes. The time period will depend on the significance of the non-compliance and will be negotiated during the on-site exit meeting.

Surveillance visits, to confirm that the management systems are continuing to operate effectively and meeting accreditation criteria, are carried out annually between the full technical reassessments. Any CARs raised must also be corrected promptly.

Once compliance has been demonstrated within the agreed time interval, IANZ formally confirms continued accreditation.

4.11 Extension of Accreditation Scope

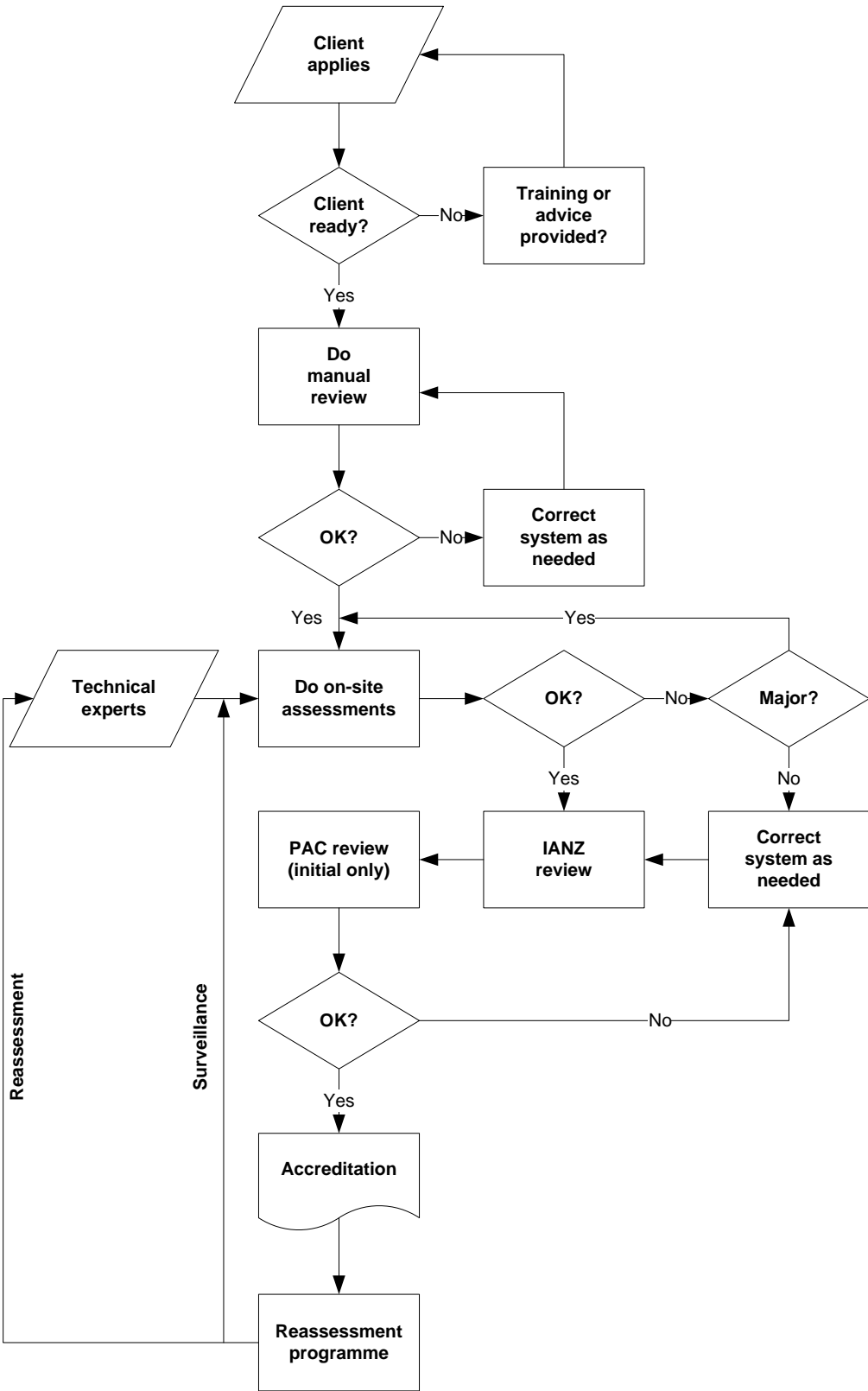
Accredited organisations may apply to have their scope of accreditation changed at any time. An extension to the range of accredited services or the addition of a new approved signatory, will usually require IANZ to carry out a limited assessment with a technical expert. Such a visit will be chargeable. If extensions to scope (or signatories) can be delayed until the next scheduled reassessment visit, such extra charges may be reduced. If CARs raised at such visits remain un-cleared more than one year later, an additional assessment will be needed before accreditation for the extension can proceed.

4.12 Suspension and Withdrawal of Accreditation

If routine reassessments, surveillance visits or special assessments reveal that an organisation's systems no longer meet IANZ's criteria for accreditation, or if the organisation refuses to carry out requested corrective actions either at all, or within the specified time, then accreditation may be suspended or withdrawn. The IANZ decision to suspend or withdraw will normally be enacted after 48 hours to give the organisation the opportunity to challenge and correct any error of fact that led to the decision. Accreditation may also be suspended when an organisation, through no fault of its own, is temporarily unable to comply with the criteria for accreditation (e.g. when all of its approved signatories or key technical personnel leave). The management of accredited organisations is expected to plan its staff resources, as far as it can, to avoid such occurrences.

Following suspension of accreditation, an organisation will need to be reassessed by IANZ to confirm that the criteria for accreditation are being met before accreditation can be reinstated. This will normally involve an on-site assessment but will depend on the original reasons for the suspension. Following withdrawal of accreditation, the organisation will need to reapply for accreditation and undergo initial assessment before regaining accreditation.

4.13 Accreditation Process Chart



Section B: Rights and Duties of Accredited Organisations

5 Conditions of Accreditation

5.1 Duties of Applicant and Accredited Organisations

- (a) Organisations must have a documented management (technical and quality) system that meets all of the requirements of the criteria for accreditation in the relevant technology area. That is:
- (i) the relevant general criteria for the selected accreditation programme;
 - (ii) the specific and supplementary criteria document(s) for the relevant technology and;
 - (iii) this document.

The management system must operate in the way it is documented. Organisations undertake to adapt their practices to changes in the requirements for accreditation, as set out in Section 5.2(h).

- (b) Organisations must allow IANZ assessment teams reasonable access to their premises, facilities, resources, operations, procedures, records and staff so that IANZ can effectively assess the quality and technical systems and activities.
- (c) Where required for the conduct of an effective assessment by IANZ, organisations shall arrange for the witnessing of its accredited activities (or activities for which accreditation are sought). These may be at the site(s) of its clients or at other locations.
- (d) Organisations must pay all reasonable fees, charges and expenses relating to the assessments conducted (initial and subsequent assessments) and to the on-going maintenance of the accreditation by IANZ. Failure to do so may result in the suspension or withdrawal of the accreditation and a requirement for any further fees to be paid in advance.
- (e) Organisations must maintain impartiality and integrity in their dealings with clients, with other interested parties and with all those involved in the accreditation activity. Where applicable, organisations must provide to IANZ access to those documents that provide insight into the level of independence and impartiality of the organisation from its related bodies.
- (f) Accredited organisations may make claim to being accredited (or make reference to the accreditation in any advertising or communication medium) only for work covered by the scope of technical activities for which accreditation has been granted by IANZ and only if that work has been carried out in accordance with the IANZ criteria. Accredited and applicant organisations may not make any statement about current or prospective accreditation that IANZ considers misleading or which is not authorised. Organisations may not use their accreditation in such a way as to bring IANZ into disrepute.
- (g) Accredited organisations must not use their accreditation to imply approval by IANZ of any product or item that has been tested or calibrated or inspected.
- (h) Accredited organisations need to ensure that the reports or certificates issued (or parts of them) are not used in a way that could mislead clients or others.
- (i) Accredited organisations must notify IANZ promptly of changes in their organisation's status or operations such as:
- (i) Loss of approved signatories, key technical personnel or other staff authorised to release technical work;
 - (ii) Changes in senior personnel duties and responsibilities (including change of Authorised Representative);
 - (iii) Significant changes in accommodation and/or equipment;
 - (iv) Changes in legal, commercial or organisational status;
 - (v) Changes in policies and procedures.

Should IANZ decide these changes could have affected the compliance of the accredited organisation with the accreditation criteria, then an assessment may be carried out to confirm that the requirements continue to be met.

Accredited organisations must not vary the technical operations or facilities covered in the scope of accreditation (Schedule to Certificate of Accreditation) during the period between assessments, unless notice is given to IANZ in writing and IANZ has confirmed that such changes do not make the accreditation invalid.

Note: The purpose of this clause is to ensure that no amendments are introduced that will reduce the technical validity or effectiveness of the accredited operations. It should not restrict the improvement or development of systems or operations. The size or significance of changes should be considered before IANZ is informed. In any case, IANZ will review all changes at each surveillance assessment or reassessment.

- (j) The IANZ accreditation symbols and the terms “Accredited Laboratory”, “Accredited Calibration Laboratory”, “Accredited Radiology Service”, “Accredited Proficiency Testing Provider” or “Accredited Reference Material Producer” shall be used only under the conditions outlined in Appendix 1.
- (k) If accreditation is withdrawn (by either the accredited organisation itself or by IANZ), the organisation must immediately stop using the IANZ accreditation symbol and the term “Accredited Laboratory”, “Accredited Calibration Laboratory”, “Accredited Radiology Service”, “Accredited Proficiency Testing Provider” or “Accredited Reference Material Producer”, and all advertising material which contains the term or the symbol or refers to them. Any other documents the accredited organisation has which refer to accreditation (such as the Certificate(s) of Accreditation, Schedule(s) to the Certificate of Accreditation or display plaques) must be returned to IANZ or destroyed.
- (l) Organisations temporarily unable to meet accreditation requirements may be asked by IANZ to cease using the endorsement and the term “Accredited Laboratory” or the other terms in (k). In such circumstances, organisations will also be asked not to claim compliance with the criteria for accreditation until IANZ is satisfied that they are again meeting the requirements or pending the result of any appeal made.

If accredited organisations fail to comply with such a request, IANZ may:

- (i) Suspend accreditation or;
- (ii) Withdraw accreditation or;
- (iii) Decline to grant or renew accreditation or;
- (iv) Reduce the scope of accreditation or;
- (v) Decline to extend the scope of accreditation.

Such decisions and the grounds for them will be communicated in writing. Compliance with these decisions will be reviewed at routine surveillance and reassessment visits.

- (m) IANZ may withdraw or decline to grant or renew accreditation if an organisation becomes bankrupt or makes any arrangements or composition with its creditors, or enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction), or has a receiver appointed, or is sold or is taken over. Such decisions and the grounds for them will be communicated in writing by IANZ. In addition, IANZ may require the organisation to stop displaying its accreditation certificate during this period and to refrain from any reference to itself as an IANZ accredited organisation.

5.2 Rights of Applicant and Accredited Organisations

- (a) IANZ accreditation is open to all organisations that come within the scope of existing IANZ accreditation programmes, regardless of size or professional affiliations.
- (b) IANZ will confine its requirements, assessments and accreditation decisions to the scope of accreditation requested.
- (c) Applications will normally be acknowledged within 10 working days of receipt and applicant organisations will be sent a receipted tax invoice for the application fee paid, or invoiced if payment not submitted with the application.
- (d) An estimate of time costs and expenses (where relevant) for assessment and surveillance activity may be provided prior to each of the IANZ visits. Where an organisation is not well prepared for the assessment, the assessment cost may well be higher than the estimate.
- (e) IANZ will endeavour to report the results of each assessment within 10 working days of the date of the visit. If there are delays, this will be clearly communicated to the organisation.
- (f) IANZ will attempt to respond to written communications within 10 working days.

- (g) Upon the granting of accreditation, IANZ will issue a Certificate of Accreditation and will publish on its website the details of its scope of accreditation. Accreditation certificates remain the property of IANZ. Up-dates to the scope of accreditation will be provided after each assessment activity and will be published on the IANZ website.
- (h) IANZ will notify accredited organisations of any changes in the criteria for accreditation and allow reasonable time to adjust procedures to meet the new requirements.
- (i) Accreditation is renewable annually subject to meeting the requirements in Section 5.1.
- (j) Organisations have the right to veto any PAC member or technical expert who may be considered to have a conflict of interest when considering applications for accreditation or when conducting assessments.
- (k) Complaints about or appeals to IANZ can be made to the Chief Executive (see Section 6 below).
- (l) On request, IANZ will provide information about sources of acceptable measurement traceability for the scope of accreditation being sought.
- (m) IANZ can provide up to date information about those organisations with which it has mutual recognition arrangements and where acceptance of reports and certificates should be facilitated by such arrangements.

5.3 Confidentiality

IANZ requires its staff, technical experts, advisory committee members and Council members to abide by a code of ethics, professional standards and confidentiality. They formally agree to keep information about applicant and accredited organisations confidential and to declare any conflicts of interest.

Until accredited, IANZ will treat all organisations' applications as confidential. Once accredited, IANZ will publish the scope of accreditation on its website at www.ianz.govt.nz.

5.4 Accreditation Fees

Accreditation attracts fees as follows:

- (a) Application Fee;
- (b) Assessment Fee (hourly charge);
- (c) Assessment Expenses (at cost or included in an annual accreditation fee);
- (d) Annual Administration Fee;
- (e) International levy (where applicable).

Current fees are set out in separate fee schedules which are freely available on the IANZ website at www.ianz.govt.nz or upon request.

6 Appeals and Complaints Procedures

Appeals and complaints fall into three categories:

- (a) Appeals about IANZ decisions;
- (b) Complaints about the activities of accredited organisations;
- (c) Complaints about IANZ activities.

If any person or organisation wishes to complain or appeal about IANZ activities or decisions, or the activities of accredited organisations, these should be in writing and sent to the Chief Executive of IANZ. Verbal complaints to the Director or any other IANZ staff member may be acted upon, but a written complaint ensures that relevant information is provided in a logical manner.

6.1 Appeals about IANZ Decisions

An appeal may be made about any IANZ assessment decision or accreditation decision, such as:

- (a) Those involving the assessment process, including application;
- (b) IANZ technical decisions, including corrective action requests raised and signatory approvals;
- (c) Denial of accreditation;
- (d) Suspension of accreditation or part of the accreditation scope;

- (e) Withdrawal of accreditation;
- (f) Any other action that impedes accreditation.

In the first instance, the person or organisation seeking an appeal should attempt to resolve any technical appeals with the Lead Assessor or the IANZ Programme Manager for the field of technology concerned.

When IANZ receives an appeal about an accreditation decision, the General Manager - Accreditation Services (GMAS) will appoint an appropriate and competent person who is independent of the subject of the appeal, to investigate it. The investigation will consider whether:

- Current IANZ policies and procedures have been properly followed;
- Current IANZ policies and procedures are adequate and appropriate;
- Accreditation decisions have been soundly based on objective evidence.

The result of the investigation and any proposed actions on the part of IANZ will be reported to the person or organisation who lodged the appeal.

If not satisfied with the IANZ response to the appeal, the complainant may approach the Chair of the Accreditation Advisory Committee for further investigation. The Chair of the Accreditation Advisory Committee, following consultation, will make the final decision and recommend the appropriate action for the GMAS to take.

The results of these higher investigations will also be reported to the person or organisation who lodged the appeal.

Contact details for the Chair of the Accreditation Advisory Committee are available from IANZ.

6.2 Complaints about Accredited Organisations

It is the policy of IANZ that accredited organisations are ultimately responsible for the quality of their own services. They should deal appropriately through their own complaints procedures with complaints from customers or competitors.

When IANZ receives a formal complaint about an accredited organisation e.g. from a customer or a competitor, the Chief Executive will appoint an appropriate person to investigate it. Initially, the IANZ role will be to assist the complainant and the accredited organisation to negotiate a satisfactory outcome.

IANZ will then check at the next assessment that the organisation's response and corrective actions resulting from the complaint were appropriate and effective. IANZ will also investigate the substance of the complaint to determine whether the organisation's operations, facilities and procedures continue to comply with the criteria for accreditation.

If a customer is unable to resolve a quality problem through liaison with the accredited organisation, this may be taken into account in deciding how soon to make the next reassessment.

The results of IANZ investigations and any proposed actions will be reported by the appointed person to the accredited organisation and to the complainant.

If either the accredited organisation or the complainant is not satisfied with the IANZ response, the complaint may be referred to the Accreditation Advisory Committee for further investigation. The results of this investigation will also be reported to the accredited organisation and to the complainant.

6.3 Complaints about IANZ Activities

Any complaints about the performance or behaviour of IANZ services or staff will be investigated by the Manager - Quality and Compliance, on behalf of the Chief Executive. The complainant will be advised of the result of the investigation and of any corrective actions taken.

Appendix 1

Rules for the Endorsement of Reports and References to Accreditation

Endorsement of Reports

IANZ encourages accredited organisations to make reference to their accreditation in reports, certificates or other documents produced. A report carrying the IANZ accreditation symbol (see IANZ accreditation symbols on page 19) or any combination of the words “IANZ”, “IANZ Accredited”, “Accredited Organisation”, etc, is referred to as an IANZ endorsed report. Such endorsed reports enjoy wide acceptance in New Zealand, and overseas through a network of formal mutual recognition arrangements between IANZ and overseas equivalents.

Accredited organisations may endorse reports as long as they meet the criteria for accreditation. The rules for endorsement allow organisations to mix both accredited and non-accredited results as long as the non-accredited results are clearly marked as such.

Rules for Accredited Organisations

- (a) When accredited organisations wish to endorse a report they must use the IANZ accreditation symbol of the relevant programme e.g.
- (i) Accredited Laboratory;
 - (ii) Accredited Calibration Laboratory;
 - (iii) Accredited Radiology Service;
 - (iv) Accredited Proficiency Testing Provider, or;
 - (v) Accredited Reference Material Producer.

Accredited Inspection Bodies and accredited Building Consent Authorities can also use their respective IANZ accreditation symbol, and the rules governing their use are detailed in the IANZ publications *Procedures and Conditions for Inspection Body Accreditation (AS 3)* and *Procedures and Conditions for Building Consent Authority Accreditation (AS 4)* respectively.

Registered GLP Compliant facilities can also use the Registered GLP Compliant symbol and the rules governing its use are detailed in the IANZ publication *Procedures and Conditions of GLP Registration (AS2)*.

Registered Conformity Assessment Bodies which are accredited will use their accreditation symbol. Those which are not accredited may not use an IANZ accreditation symbol.

- (b) An endorsed report must be signed or otherwise authorised by an approved signatory/key technical person for those accreditation programmes where the concept is relevant.
- (c) When it is impractical to display the programme accreditation symbol, accredited organisations may use a written description to promote their accreditation status, such as “Accredited by IANZ” or “IANZ accredited (laboratory / calibration laboratory / radiology service / proficiency testing provider / reference material producer)”.
- (d) When an accredited organisation’s scope of accreditation includes all the activities to be reported in an endorsed report, the accreditation symbol, together with the standard statement that the work has been performed within the scope of accreditation, will make up the endorsement.
- If accredited organisations wish to include in the same endorsed report both accredited and non-accredited results, they must.
- (e) Endorse the report with the programme accreditation symbol together with the statement that not all results are IANZ accredited, including how non-accredited results are marked in the report (see Example 2, page 19)
- A report must have the results of at least one accredited test (or other activity) or it cannot be endorsed at all and cannot contain any reference to IANZ.
- (f) When accredited organisations wish to endorse a report containing expressions of professional opinion, interpretations of results or other statements, then these must be directly based on technical results contained, or referred to, in the report and should be placed as close as practicable to those results. In some fields of technology, such opinions may not be endorsed. Please contact IANZ for further information.

- (g) When accredited organisations sub-contract work to another accredited organisation (including remote branches of their own organisation), the sub-contracted results may be incorporated into an endorsed report, provided the other organisation has endorsed the work concerned and provided that there is a clear indication in the endorsed report that the work was sub-contracted. Where the sub-contractor is not accredited, the sub-contracted results must also be identified as not accredited as described in clause (e) above, as well as being identified as being sub-contracted results. Note that sub-contracted calibrations may not be incorporated by the contracting calibration laboratory. The sub-contracting laboratory's calibration report or certificate must be issued in the name of the client.
- (h) When test results are merged from a number of separate organisations (or branches of the same organisation) into a single consolidated report, the report may be endorsed provided that it complies with the requirements in (g) above for sub-contracted work.
- (i) If an accredited organisation issues a report from a site within the company other than where the work was carried out e.g. a head office, such a report may be endorsed:
- If it meets all other requirements for endorsed reports
 - If it carries (with their approval) the signatures, facsimile signatures or typed names of the appropriate approved signatories / key technical personnel from the organisation
 - If its release is authorised by a person at the issuing site approved by IANZ to take responsibility for remotely issued reports
 - If copies of the final report are accessible at both the issuing site and the contributing locations.
- (j) If accredited organisations use the accreditation symbol on their letterhead and/or other corporate stationery, they must not report results or professional opinions on that stationery unless the report also complies with the requirements set out above.

Accredited Laboratories are able to take advantage of the IANZ membership of the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement (MRA) by using the international laboratory accreditation mark registered world-wide by ILAC. The use of this combined ILAC MRA mark (alongside the IANZ accreditation symbol) is subject to a specific administrative agreement between IANZ and the accredited laboratory, details of which may be obtained from IANZ.

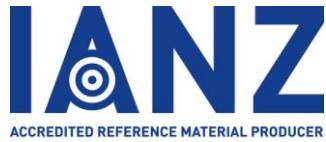
References to Accreditation

IANZ encourages accredited organisations to advertise their accredited status on other documentation / media by using the IANZ accreditation symbol or by other references to their IANZ accreditation. Such documentation may include websites, publicity or advertising material, brochures and organisation publications, technical literature, business reports, quotations or proposals for work, or the like,

Such references to accreditation must not be in any way misleading. For example:

- (i) The claims of IANZ accreditation can only be related to or associated with the services covered by the scope of accreditation (including, where relevant, accredited sites contained therein). The claims cannot suggest accreditation of other activities the organisation may be involved in that are not in the scope of IANZ accreditation (nor activities at sites not covered by the scope of accreditation). In proposals or quotations, it may be necessary to distinguish activities and/or sites that are covered by the scope of accreditation from those that are not;
- (ii) The IANZ accreditation symbol or accreditation claim cannot be affixed to an item or product or used to imply that a product or item has been certified;
- (iii) The IANZ accreditation symbol or accreditation claim cannot be used to imply IANZ accepts responsibility for the activities undertaken, or for any opinion or interpretation derived from them, or that IANZ approves the product or item subject to the accredited activity.

Accreditation Symbols



Endorsement Statements

Example 1



All tests reported herein have been performed in accordance with the laboratory's scope of accreditation



All measurements reported herein have been performed in accordance with the laboratory's scope of accreditation

Example 2



Tests indicated as not accredited are outside the scope of the laboratory's accreditation



Measurements indicated as not accredited are outside the scope of the laboratory's accreditation

Note: Accredited organisations are reminded that any use of any of these symbols or a reference to IANZ in words is an endorsement. Also, where the words are used they must only be used in conjunction with the appropriate symbol.