

# **Procedures and Conditions of Accreditation**

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## Scope

“Procedures and Conditions for Accreditation” explains the structure of International Accreditation New Zealand (IANZ) and the procedures and conditions of accreditation by IANZ. After briefly introducing IANZ, Section A overviews the Accreditation Programmes before discussing accreditation procedures in detail. Section B describes the rights and duties of accredited organisations.

“Procedures and Conditions for Accreditation” replaces the Telarc New Zealand publication “Laboratory Accreditation in New Zealand”.

## Section A: Accreditation Procedures

### 1 Introduction

International Accreditation New Zealand is the national technical accreditation body, a multi-disciplinary agency with internationally recognised expertise in accreditation programme management.

Accreditation entails examination of an organisation’s quality system together with a detailed on-site assessment of the technical competence of key staff and of the methods they use. Assessment teams normally consist of one IANZ quality system assessor (the lead assessor) and 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 your commitment to these standards.

IANZ operates accreditation programmes for the following:

- Laboratories
- Inspection Bodies
- Radiology Practices
- Pharmacies

IANZ also registers:

- Laboratories meeting the OECD Principles of Good Laboratory Practice
- Conformity Assessment Bodies designated for CE marking.

Laboratory and Inspection Body accreditations are offered in a number of fields of technology. Similarly Radiology Service and Pharmacy accreditations cover a number of different disciplines. Details of these are available from IANZ.

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

## 2 Structure

Established by Act of Parliament in 1972, the Testing Laboratory Registration Council is IANZ’s parent body. The Council is a not-for-profit, user funded body 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 nine 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 Chief Executive Officer, the Director of IANZ.

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

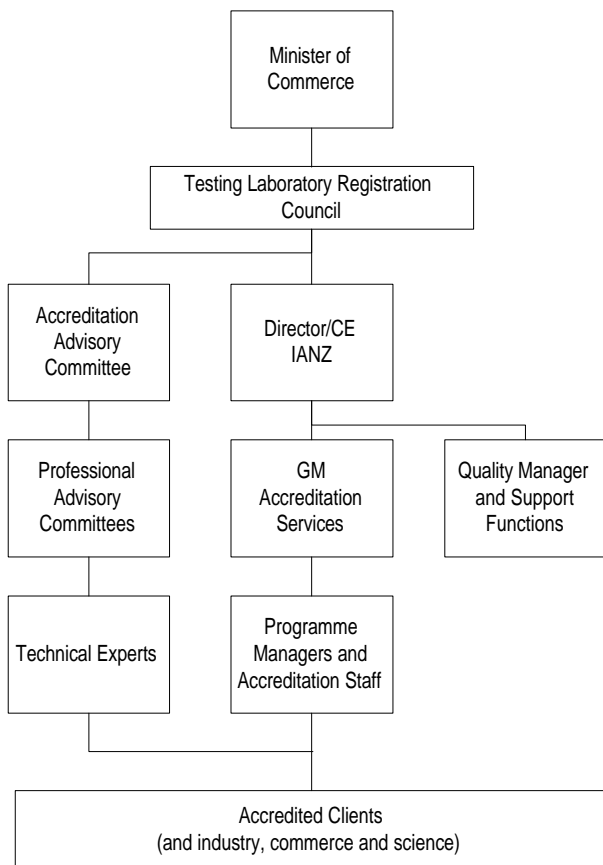
The Accreditation Advisory Committee (AAC) is a Council-appointed committee of experts assisting IANZ in the operation of the Accreditation Programmes. Its functions are:

- To provide IANZ with liaison and feedback from the New Zealand technical community.
- To review with IANZ, the general criteria for accreditation in all fields of technology, as well as maintain consistency across specific technical documents for each field.
- To consider with IANZ, national and international developments in accreditation.
- To function as an independent expert body which can be consulted by Council for decisions on any appeals arising from accreditation activities.
- To assist the General Manager, Accreditation Services, where required, in the establishment of ad hoc professional advisory committees in response to particular technical questions.

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:

- Technical review of assessment reports and responses from applicants for accreditation.
- Approval of specific criteria documents.
- Approval of technical experts.
- Providing general technical advice in the area of technology concerned.

## Organisation Chart



### Laboratories

**ISO/IEC 17025 (previously ISO/IEC Guide 25):** *General requirements for the competence of testing and calibration laboratories.*

### Inspection Bodies

**ISO 17020 (previously ISO/IEC Guide 39):** *General requirements for the acceptance of inspection bodies or*  
**EN 45004:** *General criteria for the operation of various types of bodies performing inspection.*

### Radiology Services

A version of **ISO/IEC 17025** modified specifically for radiology services.

### Pharmacies

A version of **ISO/IEC 17025** modified specifically for Pharmacies.

### 3.3 Specific 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 accepted good practice for that particular scientific discipline or technology. Where needed these are defined, along with the IANZ requirements for approved signatories, in IANZ Specific Criteria documents. Approved signatories are staff members recognised by IANZ as competent to release results and/or authorise reports and other information.

## 3 Operational Standards

### 3.1 IANZ Operational Standards

The operation of the IANZ Laboratory, Radiology Service and Pharmacy Programmes complies with the requirements of the international standard **ISO/IEC Guide 58: Calibration and testing organisation accreditation systems - General requirements for operation and recognition.**

The operation of the Inspection Body Accreditation Programme complies with the requirements of the international standard **ISO/IEC 17010: General requirements for bodies providing accreditation of inspection bodies.**

IANZ Accreditation Programmes are subject to regular internal audit, as well as external audit by overseas accreditation bodies with which we have mutual recognition. This ensures compliance with these standards.

### 3.2 Accreditation Standards

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

## 4 Accreditation Procedures

### 4.1 Overview

Once your organisation has written its technical and quality systems to comply with the *NZ Code of (Laboratory, Radiological, Pharmacy, Inspection) Management Practice* (ie the IANZ version of ISO 17025 for testing, radiology and pharmacy and of ISO 17010 for inspection), and relevant Specific Criteria, your application for accreditation can be made to IANZ. A schematic overview of the accreditation procedure is shown in the flowchart 4.11.

### 4.2 Information and Preliminary Discussions

Information about the IANZ Accreditation Programmes is freely available upon request as are copies of the *Codes and Specific Criteria* relevant to the organisation's activities. In addition, our accreditation staff are available for advice and assistance.

You may request an advisory visit to your premises by an IANZ staff member to review your existing systems and procedures and/or to explain accreditation in more detail. This service is provided at our normal hourly professional fee plus expenses. We can advise on your readiness for the initial assessment and also on any aspects of your quality systems that need further

development.

If your organisation has had no formal contact with IANZ in the past we strongly recommend such a visit. Our 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

Applications must be accompanied by the application fee detailed in the current issue of the IANZ relevant programme fee schedule.

Before the initial assessment, it is essential that enough background information is provided to IANZ to enable us to select appropriate technical expert(s) and to brief them prior to their visit to your 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 you need to provide in the questionnaire is:

- The classes of test/inspection for which you are seeking accreditation (Laboratory and Inspection Body programmes particularly). These are detailed in the IANZ specific criteria document for your particular technology.
- The staff members you wish to nominate as IANZ approved signatories or key technical personnel.
- The test or inspection procedures or other work methods you use within each technical area.

Each application is allocated to the appropriate IANZ Programme Manager (PM) for the field of technology concerned. The PM will designate an Assessment Coordinator (Lead Assessor) who will contact you to arrange a suitable date for the assessment and to discuss the proposed technical experts.

#### 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 our point of contact with you and is known as the Authorised Representative. All correspondence, invoices, etc which we send to your 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 operations of its accreditation 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 assessment entry and exit meetings.

#### 4.5 Documentation Review

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

#### 4.6 Approaching the 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. Our 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 your staff and our assessment team.

IANZ maintains a panel of specialist 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 technical experts. When acting on our behalf, the technical expert does not represent their employer or any other organisation with which they may be associated.

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

#### 4.7 The Assessment Procedure

The objective of our assessment is to confirm that you are actually doing what your manuals say you will. During its on-site visit, the assessment team will focus on your technical operations, your quality system, the competence of applicants for signatory approval and key technical personnel and on the methods you use. Information gathered will include, but is not limited to, review of records, discussions with management and signatory personnel and the observation of activities within the requested scope of accreditation. The team may wish to witness tests or other work relevant to that scope.

Most assessments take one working day 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 your senior staff. This entry meeting

provides an opportunity for:

- the timetable and scope of the assessment to be finalised
- a review of the Accreditation Questionnaire
- resolution of any immediate queries that the assessors or staff may have.

You 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 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 your representatives are given this summary including details of any areas of non-compliance that have been found and guidance on correcting them. All findings will be fully discussed with you before the team leaves.

Within ten working days of the visit, you will receive a comprehensive written report on the assessment findings which were discussed with you at the exit meeting. The report will place the findings into two categories; Corrective Action Requests (CARs) and Recommendations:

- **CARs** are actions that the organisation must carry out before accreditation can be granted. CARs usually relate to non-compliances with the *Code* or *Specific Criteria*.
- **Recommendations** are actions that the organisation is urged to carry out in the interests of good practice, but are not considered CARs.

The IANZ Assessment Coordinator (AC=Lead Assessor) will monitor your progress in carrying out the required actions. Once the AC is satisfied that all conditions for accreditation have been cleared, they will prepare a report on the assessment for consideration by the PAC.

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. The recommendation includes the particular tests or types of activities for which accreditation is to be granted and the names of staff who are to be awarded signatory approval. 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 in the New Zealand Accreditation Directory. Accreditation certificates remain the property of IANZ.

Accreditation allows your organisation to endorse relevant

certificates, reports or other relevant outputs in the name of IANZ. The detailed requirements for IANZ endorsement are given in the Appendix to this publication. Endorsement with the IANZ logo is not compulsory but is strongly encouraged because it adds credibility to your work.

#### 4.8 Continuation of the Initial Assessment

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

You may ask for a special assessment to approve new signatories or new work at any time. If CARs raised at such a visit remain uncleared more than a year later, an additional assessment will be needed before accreditation for the extension can proceed.

#### 4.9 Scope of Accreditation

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

Accreditation is normally granted only for work that is performed regularly and for which you are properly equipped and have shown your competence. Your 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 you wish to be accredited for things you rarely do, your staff will need some means of keeping up to date with those activities. This can include comparative tests within your organisation or with others, participation in inter-laboratory comparison programmes or regular testing/inspection of artifacts.

In granting accreditation we will specify the following details in your scope of accreditation:

- the products and services provided
- methods used (eg Class 2.06: Chemical tests on cement in accordance with NZS 3122:1995)
- ranges of measurements and least uncertainties for calibrations (eg Class 5.21 Calibration of Masses over the range 50 to 300g to a least uncertainty of 2 parts per million at 95% confidence)
- either uncertainty or limits of detection for some types of tests.

The available activity classes (e.g. classes of test) are detailed in each *Specific Criteria* document for your 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.

You may carry out calibrations and commission checks on your own test and measuring equipment providing you are equipped to do so and have acceptable written methods. Calibrations for other organisations will not be accepted by IANZ unless you are accredited for them.

**4.10 Surveillance and reassessment**

Once you gain accreditation your organisation enters our programme of scheduled reassessment visits. These visits ensure that your 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 appropriate.

Full technical (routine) reassessments are usually carried out at three yearly intervals although for medical testing laboratories intervals are 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 procedures. Reporting procedures also resemble those at initial assessments, but once you are accredited there is a limit on the time you may take to carry out any requested changes.

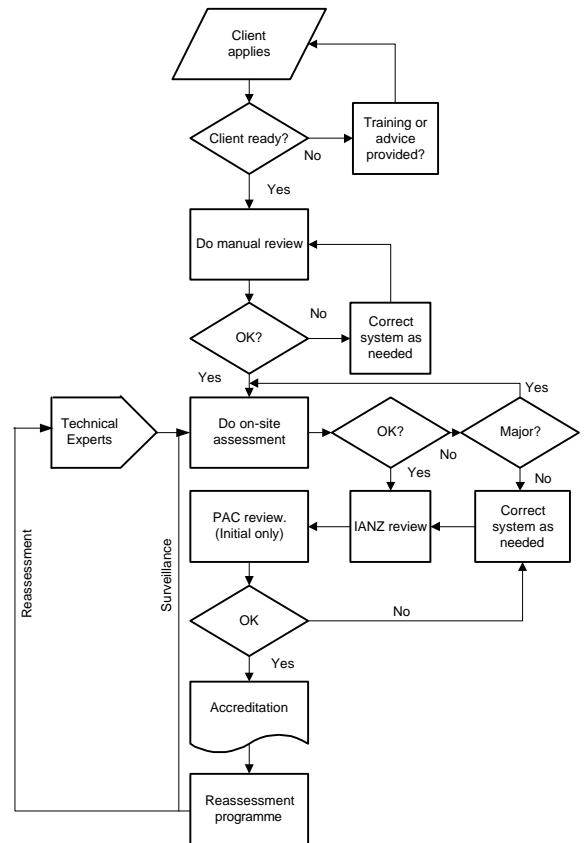
Surveillance visits, to confirm that your systems are operating effectively and meeting our criteria, are carried out annually between the full technical reassessments. Surveillance visits are normally reported on site. Any conditions raised must also be corrected promptly.

Once compliance has been demonstrated within the agreed time interval, IANZ grants your continued accreditation.

You may apply to have your scope of accreditation changed at any time. If you want to extend your range of services, or add a new signatory, we will usually have 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 scheduled reassessment visit, such extra charges may be reduced.

If special assessments or routine reassessments 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 in the specified time, then accreditation may be suspended or withdrawn. 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. Your management should plan its staff resources, as far as it can, to avoid such occurrences.

**4.11 Assessment Procedures Chart**



## Section B: Rights and Duties of Accredited Organisations

### 5 Conditions of Accreditation

#### 5.1 Duties of Applicant and Accredited Organisations

- a) Your organisation must have a written quality system that meets all of the requirements of the relevant criteria for your technology area. That is, the relevant *Code* for your accreditation programme, the *Specific Criteria* document(s) for your technology and this document. Your quality system must operate in the way it is documented.
- b) Your organisation must allow our assessment team reasonable access to your premises, facilities, resources, operations, procedures, records and staff so that we can effectively assess your quality and technical systems and activities.
- c) You must pay all reasonable fees, charges and expenses relating to the initial assessment and to accreditation of your organisation and to subsequent assessment activity by IANZ. Failure to do so may result in the suspension or withdrawal of your accreditation, and a requirement for any future fees to be paid in advance.
- d) Your organisation must maintain impartiality and integrity in its dealings with clients, with other interested parties and with all those involved in the accreditation activity.
- e) You may claim to be accredited (or make reference to your accreditation in any advertising or communication medium) only for work covered by the scope of technical activities which you have accredited by IANZ and only if that work has been carried out in accordance with the IANZ criteria. You may not make any statement about your accreditation that IANZ considers misleading, or which is not authorised. You may not use your accreditation in such a way as to bring IANZ into disrepute.
- f) You must not use your accreditation to imply approval by IANZ of any product or item you have tested or calibrated or inspected.
- g) You must ensure that the reports or certificates you issue (or parts of them) are not used in a way that could mislead your clients or others.
- h) You must notify IANZ promptly of changes in your organisation's status or operations such as:
  - loss of approved signatories or other staff authorised to release technical work
  - changes in senior personnel duties and responsibilities (including change of Authorised Representative)
  - significant changes in accommodation and/or

- equipment
- changes in legal, commercial or organisational status
- changes in policies and procedures.

*(If we decide these changes could have affected the compliance of your organisation with the accreditation criteria, then we will carry out an assessment to confirm that you still meet the requirements.)*

- i) You must not vary the technical operations or facilities covered in the scope of accreditation (Schedule to the Certificate of Accreditation) during the period between assessments, unless you have given us notice in writing and we have confirmed in writing that such changes do not make your accreditation invalid.

*(The purpose of this clause is to ensure that no amendments are introduced that will reduce the technical validity or effectiveness of your operations. It should not restrict the improvement or development of your 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 logo and the term "Accredited Laboratory", "Accredited Inspection Body", "Accredited Radiology Service" or Accredited Pharmacy" shall be used only under the conditions outlined in Appendix 1.
- k) If your accreditation is withdrawn either by you or by IANZ then you must immediately stop using the IANZ accreditation logo and the term "Accredited Laboratory", "Accredited Inspection Body", "Accredited Radiology Service" or "Accredited Pharmacy" and all advertising material which contains the term or the logo, or refers to them. Any other documents you have which refer to accreditation (such as the Certificate of Accreditation, Schedules or display plaques) must be returned to IANZ or destroyed.
- l) If your organisation is temporarily unable to meet the accreditation conditions, IANZ may ask you to stop using the endorsement and the term "Accredited Laboratory" or the other terms in k). You will also be asked not to claim compliance with the criteria for accreditation until we are satisfied that you are again meeting the conditions, or pending the result of any appeal made by your organisation.

If your organisation fails to comply with such a request, IANZ may:

- suspend accreditation, or

- withdraw accreditation, or
- decline to grant or renew accreditation, or
- reduce the scope of accreditation, or
- decline to extend the scope of accreditation.

Such decisions and the grounds for them will be communicated to you in writing.

Your 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 your 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 to you in writing. 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 our existing 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) Your application will normally be acknowledged within 10 working days of receipt and you will be sent a receipted tax invoice for the application fee paid.
- d) An estimate of time, costs and expenses (where relevant) for assessment and surveillance activity will be provided prior to each of our visits. Where an organisation is not well prepared for the assessment, the assessment cost may well be higher than the estimate.
- e) We will report the results of each assessment to you within 10 working days of the date of the visit.
- f) We will respond to your written communications within 10 working days.
- g) Upon the granting of accreditation, IANZ will issue you with a Certificate of Accreditation and will publish in the New Zealand Accreditation Directory the fact that your organisation has been granted accreditation, together with details of its scope of accreditation. Accreditation certificates remain the property of IANZ.

- h) IANZ will notify you of any changes in the criteria for accreditation and give you reasonable time to adjust procedures to meet the new requirements.
- i) Accreditation is renewable annually subject to your meeting the requirements in 5.1.
- j) You have the right to veto any PAC member or technical expert who you consider may have a conflict of interest when considering your application or conducting your assessment.
- k) Complaints or appeals about IANZ can be made to the Director (see 6 below).

## 5.3 Confidentiality

We require our staff, technical experts, members of advisory committees and council members to abide by a code of ethics, professional standards and confidentiality. They agree in writing to keep information about your organisation confidential and to declare any conflicts of interest.

Until you are accredited we will treat your application as confidential. Once you are accredited we will publish the scope of your accreditation in the New Zealand Accreditation Directory.

## 5.4 Accreditation Fees

Accreditation attracts fees as follows:

- Application Fee
- Assessment Fee (hourly charge)
- Assessment Expenses (at cost or included in the annual administration fee)
- Annual Administration Fee.

Current fees are set out in a separate fee schedule which is available on request.

## 6 Appeals and Complaints Procedures

Appeals and complaints fall into three categories:

- appeals about IANZ decisions
- complaints about the activities of accredited organisations
- complaints about IANZ activities.

If you wish to complain or appeal about our activities or decisions, or the activities of our accredited clients, you should put your complaint in writing and send it to the Director of IANZ. Verbal complaints to the Director or any other staff member may be acted upon but by putting the complaint in writing you can ensure that all relevant information is provided in a logical manner.

### 6.1 Appeals about IANZ Decisions

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

- assessment procedure
- IANZ technical decisions including corrective actions raised and signatory approvals

- suspension of your accreditation or part of scope
- withdrawal of your accreditation.

In the first instance, you should attempt to resolve any technical appeals with the assessment coordinator or the 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 person 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 our proposed actions, will be reported to you.

If you are not satisfied with our response to your appeal you may approach the chairman of the Accreditation Advisory Committee for further investigation. The chairman 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 you.

## **6.2 Complaints about Accredited Organisations**

It is 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 we receive a formal complaint about an accredited organisation e.g. from a customer of a competitor, the Director will appoint an appropriate person to investigate it. Initially, our role will be to assist the complainant and the accredited organisation to negotiate a satisfactory outcome.

We will then check at the next assessment that the organisation's response and corrective actions resulting from the complaint were appropriate, and effective. We 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 our 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 are 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 IANZ Manager, Quality Improvement (MQI), on behalf of the Director. You will be advised of the result of the investigation and of corrective actions taken.

## APPENDIX 1

### Rules for the Endorsement of Reports

We encourage you to make reference to your accreditation in reports, certificates or other documents you produce. A report carrying the IANZ accreditation logo (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 agreements between IANZ and overseas equivalents (see IANZ accreditation logos page 12).

You may endorse your reports as long as they meet the criteria for accreditation. Our endorsement rules allow you to mix both accredited and non-accredited results and to include statements of professional opinion in reports as long as you clearly mark the non-accredited results and opinions.

#### Rules

- a) When you wish to endorse a report you must use the logo of the relevant programme eg Accredited Laboratory, Accredited Calibration Laboratory, Accredited Inspection Body, Accredited Radiology Service or Accredited Pharmacy. Registered GLP Laboratories and Registered Conformity Assessment Bodies which are accredited will use their accreditation logo. Those which are not accredited may not use an IANZ accreditation logo.
- b) When it is impractical to display your programme accreditation logo, you may use a written description to promote your accreditation status. In these circumstances, please use one of the following:  
  
***Accredited by International Accreditation New Zealand*** (preferred option)  
  
***New Zealand Accredited (Laboratory / Calibration Laboratory / Radiology Service / Inspection Body/Pharmacy)*** (alternative option)
- c) When your scope of accreditation includes all the activities to be reported in an endorsed report, the logo, together with the standard statement that the work has been performed within the scope of accreditation, will make up the endorsement (see examples page 12).
- d) If you wish to include in the same endorsed report both accredited and non-accredited results, you must:
  - (i) endorse the report with the programme accreditation logo together with the statement that not all results or opinions are IANZ

accredited, and show how non-accredited results are marked in the report (see example 2 page 12)

- (ii) mark each non-accredited result or opinion as you have indicated in (i).
- e) If you use the accreditation logo on your letterhead and/or other corporate stationery you must not report results or professional opinions on that stationery unless the report also complies with the requirements set out above.

***Note: 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.***

#### Guidance

- a) When you want 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.
- b) When you sub-contract work to another organisation (including remote branches of your own organisation), the sub-contracted results may be incorporated into your endorsed report and covered by your accreditation, provided the other organisation has endorsed the work concerned and provided that there is a clear indication in your report that the work was sub-contracted. Where your sub-contractor is not accredited, the sub-contracted results must be identified as not accredited as described in clause d) (i) and (ii) above.
- c) 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 (b) above for sub-contracted work.
- d) If you issue 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 from your organisation

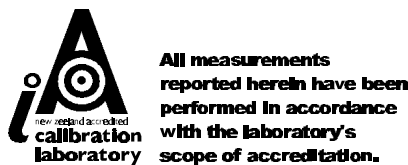
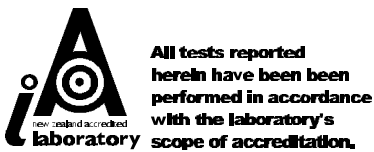
- if its release is authorised by a person at the issuing site approved by IANZ to take responsibility for remotely issued reports
  - if copies of the final report are kept at both the issuing site and the contributing locations.
- e) Accredited Laboratories sending reports/certificates to Australia are able to take advantage of our mutual recognition agreement with the National Association of Testing Authorities (NATA) by using the NATA and IANZ accreditation logos on their endorsed documents. More information about how you do this is available from IANZ.

## Accreditation Logos



## Endorsement Reports

### Example 1



### Example 2



## APPENDIX 2

### KEY STAFF AND APPROVED SIGNATORIES

Staff in charge of inspection bodies must have sufficient knowledge and practical experience to enable them to foresee, to recognise and to cope with any technical problem likely to arise in the course of the work of the inspection body. They must also be able to control the work of their staff. If any other persons are engaged in supervision of inspection body staff they too must have these capabilities. The qualifications and experience required of the person in charge and other staff members cannot be rigidly specified but must be appropriate to the work in which they are engaged.

It would normally be expected that senior staff members will hold tertiary qualifications in a relevant discipline. In some cases qualifications such as a Certification Board for Inspection Personnel (CBIP) qualification will be appropriate. Inspection bodies engaged in a restricted range of repetitive work may be controlled by an officer with practical experience and specific training in that work but without formal qualifications. Assistant staff members must have qualifications and experience appropriate to the work in which they are engaged. The ratio of qualified and experienced staff to other inspection body staff 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

Every inspection body must have at least one staff member who meets the requirements for an approved signatory and whose approval covers the terms of accreditation of the inspection body. The scope of accreditation is automatically limited to the sum of the scopes of its approved signatories. Accreditation automatically becomes inoperative if an inspection body loses all its approved signatories.

IANZ endorsed inspection documents must be signed by a member of the inspection body's staff to whom signatory approval has been granted by the Council. A person may be granted signatory approval either for all of the inspections included in their inspection body's scope of accreditation, or only for specific inspections relating to their area of personal expertise.

Signatory approval is not a transferable personal qualification. It lapses when an officer leaves the inspection body or has a changed role in the inspection body.

The following matters are considered when assessing the suitability of staff members for approval as signatories:

Relevant qualifications and/or experience. (If the signatories do not have relevant qualifications they must have sufficient relevant practical experience enabling them to comply with the requirements listed below)

Position in the staff structure. (Approved signatories must be

technical personnel closely involved in the day to day operations of the inspection body)

- (a) Familiarity with procedures and awareness of any limitations of these procedures. (Approved signatories must have appropriate personal experience in the inspection procedures for which approval is held. They must be aware of any limitations with regard to these procedures, and must understand the technical basis of the procedures)
- (b) Ability to make a critical evaluation of inspection results and a position in the staff structure which makes them responsible for the adequacy of inspection results. Knowledge of quality assurance procedures in the operation in the inspection body and ability to take appropriate and effective corrective action, when required
- (c) Knowledge of, and a commitment to, the IANZ requirements for signatories and for accreditation. (This will include being conversant with the NZCIMP and the requirements of this document)
- (d) Sufficient service in the inspection body to address the above points. (It is difficult to specify a precise duration of service as it is dependent on the staff member's background knowledge and experience and current role in the inspection body. It is unlikely that this period would be less than six months, but exceptional circumstances may apply).

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

Signatory approval is available to persons engaged by an inspection body as consultants, with respect to inspection work done at or from the accredited inspection body's premises, provided that there is a written agreement between the parties setting out the extent of the authority and responsibility of the consultants in relation to the inspection body. The consultants' position in relation to the inspection body must be such that they can perform their role as supervisory officers as effectively as if they were employees.

Officers of the inspection body who are not engaged full-time in the inspection body are also eligible for signatory approval, provided that the circumstances in which they are called upon to exercise their signatory function and their access to, and knowledge of, the inspection operations are such that they are able to take responsibility for the relevant inspection results.

The position and function of an approved signatory are quite distinct from those of an Authorised Representative. An inspection body may have more than one approved signatories but can only have one Authorised Representative. The Authorised Representative may only sign an inspection document bearing

the IANZ endorsement if the document is also signed by an approved signatory or if the Authorised Representative has been formally granted approved signatory status by IANZ .

## **APPENDIX 3**

### **ASSOCIATED AND SUBSIDIARY INSPECTION BODIES**

#### **Inspection Body Branches**

If an inspection body has two or more branches each of which can accept new clients or new work without reference to any of the others, then separate applications for accreditation are required from each branch together with the appropriate fees.

#### **Temporary Branches**

If an inspection body is required to establish a subsidiary branch to service a particular project or location it is termed a temporary branch and the following procedures apply. Temporary branches are divided into two categories according to the length of time for which they are established. These categories are as follows:

- a) if a temporary branch is established by an accredited inspection body for a period up to twelve months, this is regarded as a routine on-site inspection project. Such projects are covered by the inspection body's accreditation and if the temporary branch complies with the IANZ criteria for accreditation then inspection reports issued by the temporary branch may be IANZ endorsed
- (b) when a branch is to be established for a period in excess of 12 months it is regarded as being a separate branch in its own right. A separate accreditation must therefore be sought and the appropriate fees paid.