

technical guide

Assessor Guidelines

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Foreword

This publication has been prepared to provide a guideline for the conduct of **International Accreditation New Zealand** assessments. As its title implies, this is a guideline document. It is not intended to be a manual on how to undertake an assessment. It is recognised that experienced assessors will develop their own techniques and styles. It is also recognised that no two organisations are alike so no two assessments can be expected to follow precisely the same pattern. The guide should, however, be of use to newly appointed assessors and Technical Experts and should serve as a useful aide memoire for more experienced assessors.

This guide is written to assist assessors and Technical Experts in all fields of accreditation conducted by International Accreditation New Zealand.

For simplicity, the word 'organisation' is used throughout the guide, but should be understood as meaning the organisation or part organisation which is seeking accreditation from International Accreditation New Zealand, whether it be a Testing or Calibration Laboratory, an Inspection Body or Medical Imaging (Radiology).

1 The Concept of Accreditation

The Testing Laboratory Registration Council, established in 1973, operates New Zealand's laboratory, inspection body and medical imaging (radiology) accreditation programmes.

In the context of the Council's work, the term 'accreditation' means the formal recognition that an organisation is capable of meeting certain standards and is technically competent.

International Accreditation New Zealand is the operating unit of the Testing Laboratory Registration Council, and its accreditation programme is often referred to as being an independent or 'third party' accreditation programme. This is because the Council is an autonomous Crown Entity established to grant registration (accreditation) on the community's behalf. International Accreditation New Zealand does not operate as an agent of the organisation that it assesses nor as an agent for their users. However, both parties, and through them the community at large, benefit from the programme.

Accredited organisations gain a formal, public recognition of their technical competence and are able to demonstrate to their customers (users) and to appropriate regulatory bodies that they are capable of working in accordance with currently accepted standards of good management practice. Users of accredited organisations, those who must make important decisions on the basis of test or inspection results, receive an assurance of reliable, professional work.

The fundamental purpose of accreditation is therefore the granting of public recognition to those organisations whose standards of management, organisation and operation have been demonstrated to be sound within the context of their particular function.

The accreditation process must take into account the function of the organisation, including the purpose for which it has been established and the use to which its results are put. Although the basic criteria for accreditation are similar for every organisation, the manner in which these criteria are applied to any particular organisation will vary considerably depending upon the nature of the organisation.

In its approach to accreditation, International Accreditation New Zealand is always careful to relate its requirements for registration to the real needs of the organisation. International Accreditation New Zealand does not insist that an organisation maintain a standard of operation higher than that needed to achieve the reliability of results required by its clients.

It follows that by accreditation, International Accreditation New Zealand does not necessarily identify an organisation as a centre of excellence; rather it is a statement that the organisation has been shown to

possess the competence and facilities needed in its particular circumstances to produce reliable results for its customers.

It also follows that the need for and benefits of accreditation are not only related to the issuing of reports; any organisation should operate at a standard appropriate to its customers' requirements, regardless of whether or not its work results in the issuing of formal reports.

2 Assessment Objectives

The primary objective of an International Accreditation New Zealand assessment is to determine whether the organisation's operations and facilities comply with the criteria for accreditation.

A secondary objective, as defined in the International Accreditation New Zealand terms of reference, is the promotion of the development and maintenance of good practice in conformity assessment.

The use of a review by appropriate Technical Experts is the main way employed by International Accreditation New Zealand to highlight shortfalls in technical standards and to disseminate information to help promote improvement in organisational practice.

The provision of advice by assessors and Technical Experts needs to be handled with care and sensitivity, recognising that:

- (a) A very clear distinction must be made between corrective action needed to enable the organisation to meet conditions for accreditation, and advice offered as a way of further improving an already adequate aspect of the organisation's operations
- (b) The International Accreditation New Zealand staff assessor leading the assessment will be knowledgeable regarding International Accreditation New Zealand's approach to comparable situations in other organisations and will, therefore, be able to guide the Technical Expert on the appropriateness or otherwise of any advice they may wish to offer.

Ultimately, it is the Council which must make definitive decisions on any changes needed to an organisation as a requirement for accreditation, especially where such changes may involve the organisation in significant expenditure or in significant alterations to its staffing, accommodation or operational procedures.

3 The Assessment Team

3.1 Composition

The assessment team will consist of an International Accreditation New Zealand staff member who acts as the lead assessor, and one or more Technical Experts, one for each of the common ranges of specialisation found in the organisation. The Technical Experts in the team are chosen for their expertise and familiarity with the area of specialisation of the organisation.

Note: Surveillance assessments are assessments of the implementation of the organisation's quality systems, and they take place in the intervening years between full routine reassessments. They are conducted by an International Accreditation New Zealand lead assessor only.

3.2 Role of the Technical Expert

The Technical Expert is the peer reviewer of the technical aspects of the organisation. The role of the Technical Expert is to:

- (a) Examine all technical aspects of the management and operation of the organisation relevant to the scope of accreditation sought by the organisation
- (b) Assess the appropriateness of the methods or procedures employed; the adequacy of qualifications, experience and competence of the staff; the suitability of the accommodation/environment; the adequacy of equipment and the soundness of all aspects of the organisation's practice, and to keep notes of his/her observations and conclusions

- (c) In consultation with the International Accreditation New Zealand lead assessor, provide constructive advice on alternative corrections of any deficiencies noted (during the course of the assessment and in the preparation of the assessment report).

3.3 Role of the International Accreditation New Zealand Lead Assessor

International Accreditation New Zealand assessors are experienced in assessment techniques and are knowledgeable about quality management systems. They undertake up to 60 formal assessments each year. With regard to these assessments their role is to:

- (a) Assist the organisation in its preparations for assessment through the provision of advice before the formal assessment
- (b) Obtain full background information on the organisation to be assessed and provide technical information in the form of detailed briefing notes to the Technical Experts
- (c) Review the organisation's accreditation questionnaire and supporting documentation
- (d) Arrange the date and time of the assessment visit and make all necessary logistical arrangements
- (e) At the start of the assessment, introduce the assessment team to the staff of the organisation, outline the assessment procedure to the organisation staff, and assist the Technical Experts in commencing their task
- (f) Throughout the assessment, provide advice as required on International Accreditation New Zealand's policies and accreditation practices relating to the work under consideration; assist the Technical Experts in whatever way is necessary in their investigation of the organisation; ensure the thoroughness of the assessment; and ensure a consistent approach to the assessment of similar organisations
- (g) Assess the less technical aspects of the quality management systems

and, in consultation with the Technical Experts, to:

- (h) Prepare the assessment report which details the findings of the assessment team, and specifies where any corrective actions need to be taken
- (i) Present these findings to the organisation and seek to resolve any questions that arise before leaving the organisation.

3.4 Teamwork

Co-operative teamwork amongst the Technical Experts and the International Accreditation New Zealand lead assessor is important to the success of any assessment, especially if the assessment starts to become difficult.

The Technical Experts should have no hesitation in consulting the International Accreditation New Zealand lead assessor for assistance if they feel that the assessment process is being disrupted or that they are not securing the full co-operation of the organisation's staff. Similarly, International Accreditation New Zealand lead assessors have a duty to ensure that the assessment process is thorough and complete, and they may need to unobtrusively alert the Technical Experts to aspects of the organisation's operation which need to be probed further.

3.5 Appointment of Technical Experts

International Accreditation New Zealand maintains lists of Technical Experts who are drawn from the ranks of government laboratories, academic institutions, research associations, industrial laboratories and consultancies. These have been approved by one of the Professional Advisory Committees.

Technical Experts are selected for a particular assessment on the basis on their professional knowledge of, and expertise in, the particular area of technology and for their ability to investigate and evaluate an organisation's standard of quality management and operation.

Technical Experts work for International Accreditation New Zealand as individuals, not as representatives of their employers or any other organisation with which they may be associated. They mostly give of their time freely, but any expenses they incur while working for International Accreditation New Zealand in this capacity are reimbursed.

Technical Experts are completely free to accept or decline the invitation to participate in any particular assessment. They should not hesitate to exercise this right if their participation could be a source of inconvenience or embarrassment to themselves, to their employers or to the organisation to be assessed.

It is expected that Technical Experts will fully support the concept of accreditation and the principles of good conformity assessment practice embodied within the International Accreditation New Zealand criteria for accreditation. If, however, a person is invited to assist as a Technical Expert and subsequently finds that he or she does not fully agree with these requirements, then such reservations should be raised with International Accreditation New Zealand so that conflict during the assessment is avoided. Such feedback from Technical Experts is an essential element in the on-going development of accreditation criteria.

Technical Experts are free to withdraw from the assessor list at any time.

4 The Assessment Process

4.1 Types of Assessment

Within the International Accreditation New Zealand system, an assessment of an organisation can take one of a number of forms, depending upon the particular circumstances.

- (a) The **initial or initial continued** assessment of an (unaccredited) applicant organisation (IA, IC)
- (b) A **routine** reassessment or a **surveillance** assessment of an accredited organisation conducted under the annual review programme (RR, S1, S2, S3)
- (c) An **extension** assessment (EA) following an organisation's request for changes in the accredited work or in its list of approved Signatories or after a significant change in the circumstances of the organisation; or
- (d) A **special** assessment (SA) following a complaint against the organisation, the existence of a dispute over results, poor performance of the organisation in any relevant proficiency programmes, or some other factor which has reduced the level of confidence that International Accreditation New Zealand has in the organisation.

While the conduct and emphasis of any particular assessment will be determined to some extent by its purpose, the same basic principles will apply regardless of the type of assessment.

4.2 Initiation

Once the need for an assessment has been established, the International Accreditation New Zealand lead assessor responsible for the co-ordination of the assessment will:

- (a) Advise the Authorised Representative of the organisation of the impending assessment and of the names of the Technical Experts nominated and of any observers
- (b) Secure the Authorised Representative's approval of the assessment team
- (c) Contact the Technical Experts and secure their agreement to participate in the assessment
- (d) In consultation with the Authorised Representative and the Technical Experts, set the date and time of the assessment and make all necessary transport and accommodation arrangements
- (e) Where necessary (RR, EA, IA, IC), request relevant information and documentation from the organisation
- (f) Prepare the briefing notes and supply copies to the Technical Experts.

4.3 Briefing Notes

The briefing notes will include details of:

- (a) The purpose of the assessment and any pertinent information arising from previous visits or assessments
- (b) The scope of accreditation held or sought by the organisation and any variations now being requested
- (c) The work covered by this scope of accreditation
- (d) The names, qualifications, and experience of key technical staff of the organisation (usually those approved or nominated as Signatories or Key Technical Personnel)
- (e) The facilities available, including the significant items of equipment
- (f) Where applicable, typical or relevant operational procedures in use in the organisation

- (g) Where applicable, results obtained by the organisation from its participation in any relevant proficiency programmes
- (h) Any other information on the organisation or its operations which would assist the Technical Experts in their task, such as copies of test records and reports, relevant details from the previous assessment, etc.

These briefing notes, accompanied by a letter confirming the assessment arrangements and a provisional assessment timetable, are sent to the Technical Experts well in advance of the assessment date.

4.4 On-Site Assessment

Prior to the start of the assessment, it is advisable for the assessment team to meet together to plan the best approach to the assessment and their respective roles.

The journey to the organisation often provides an opportunity for such discussions but if the assessment team is not travelling together, it may be advisable for them to spend some time in private discussion at the organisation before starting the assessment.

The International Accreditation New Zealand lead assessor will normally initiate the assessment with an entry meeting with the organisation's staff, introducing the assessment team to senior staff of the organisation, outlining the planned assessment procedure and clarifying any administrative matters relating to the accreditation process, the scope of accreditation, the criteria for accreditation and the list of approved Signatories or Key Technical Personnel.

The lead assessor will also, at this early stage, attempt to put the organisation's staff at their ease, reduce any tension and allay any nervousness they may feel. He or she will seek to encourage the concept of the assessment as a team effort, with organisation and assessment team working together to achieve a common improvement goal.

The International Accreditation New Zealand lead assessor is expected to lead the assessment process and to assist the Technical Experts in managing the progression of the assessment during the day by guiding the Technical Expert. There are occasions when members of an assessment team differ in their opinions on the adequacy of some aspect of the organisation or its operations or on the nature of any corrective action required. When such differences occur, they should not be aired in the presence of staff of the organisation being assessed. If the matter cannot be resolved tactfully at the time, the assessment team should temporarily leave the issue unresolved and seek an opportunity (either during the visit or afterwards) to discuss the matter in private and, if possible, achieve consensus.

Advice to assessors and Technical Experts on various aspects of the assessment of an organisation are given in Sections 6 and 7.

It is expected that, in keeping with the 'team approach' already mentioned above, any observed non-compliances will be fully discussed with the assessee at the time they were observed to ensure all the related facts or reasons are uncovered for the assessment team.

4.5 Analysis of Assessment Findings

Once the assessment team is satisfied that it has completed the examination of the organisation, it will review the results of the assessment in private. The purpose of these discussions is to allow the team to reach a consensus on the compliance or otherwise of the organisation with the criteria for accreditation, any corrective actions required of the organisation and any advice which can be offered for improvement of the operations. These discussions also give members of the team an opportunity to review the assessment as a whole and discover any aspect of the organisation's operation which may have been overlooked or insufficiently investigated.

During this meeting the conclusions are developed for the assessment report.

4.6 Concluding the Assessment

An exit meeting is conducted with the Authorised Representative (and any organisation staff members he or she may choose to involve). In this meeting, the lead assessor advises the organisation of the outcome of the assessment and presents a draft of the assessment report. The lead assessor may call upon the Technical Experts to contribute on specific technical matters but in this meeting the lead assessor is the spokesperson for the team.

During this meeting it is emphasised that the assessment has been a sampling exercise and that every aspect of the organisation's activities has not been covered. It does not follow, therefore, that no problems exist in areas where none have been reported.

The efficient conduct of this final meeting will leave a lasting impression of the professionalism of the assessment team and the value of the assessment process. The meeting should not, therefore, be rushed. The assessment timetable should include a suitable provision for the meeting.

Although the assessment is a dialogue between the assessment team and the organisation's staff, in presenting its summary the team should not be drawn into prolonged debating of the validity of their recommendations concerning the accreditation requirements. The organisation has an opportunity to refer these matters, if necessary, directly to International Accreditation New Zealand's General Manager Accreditation Services, or the chairperson of the Professional Advisory Committee, when it responds to International Accreditation New Zealand's assessment report.

4.7 After the Assessment

There should be no need for any subsequent direct contact between a Technical Expert and the organisation on matters related to the assessment, but if such a need arises, this should be arranged through International Accreditation New Zealand. If any member of the organisation's staff contacts the Technical Expert on any matter related to the assessment (especially the outcome), the Technical Expert should advise the person concerned to contact International Accreditation New Zealand directly.

The completion of the exit meeting generally completes the Technical Expert's role in the assessment process. However, it may be necessary, if requested by the International Accreditation New Zealand lead assessor, for the Technical Expert to examine responses of a technical nature from the organisation and to help determine whether the organisation has satisfactorily fulfilled the requirements of the assessment team's report.

5 Assessment Techniques

5.1 Preparing for the Assessment

International Accreditation New Zealand provides its Technical Experts with a comprehensive set of briefing notes about the organisation to be assessed [See 4.3 above]

Technical Experts should familiarise themselves with this briefing information prior to the assessment. Many find it useful to annotate the briefing notes with their own comments and notes as an aide memoire for points that they may wish to raise during the assessment.

After reading their briefing notes, Technical Experts should contact the International Accreditation New Zealand lead assessor for the assessment if they require any additional information about the organisation or if they would like the organisation to be prepared to demonstrate any particular work for which accreditation is being sought. International Accreditation New Zealand will endeavour to supply copies of methods or procedures used by the organisation if these are not readily available to the expert.

5.2 Planning the Assessment

The lead assessor should give some thought to the sequence in which the assessment is to be carried out and the time to be spent on each aspect of the assessment including entry and exit meetings. This does not have to be rigidly adhered to but it helps both the assessment team and the organisation to schedule their work if a provisional timetable is developed.

The meeting amongst members of the assessment team prior to the start of the assessment is the best time to confirm this provisional timetable which should take into account the organisation's normal lunch and tea breaks and the finishing time for the organisation staff.

5.3 Starting the Assessment - The Opening (Entry) Meeting

The International Accreditation New Zealand lead assessor will have asked the organisation to provide a room for this initial meeting between the assessment team and the appropriate staff of the organisation. This meeting serves to introduce both groups to each other and provides an opportunity for the lead assessor to brief the organisation's personnel on the objectives and format of the assessment and to confirm the day's timetable.

At this stage, the assessment team should determine whether the organisation wishes to introduce any last minute changes to the information supplied in the briefing notes and should ensure that all personnel who are to be interviewed for Signatory approval are available.

As already mentioned, one of the most important functions of this opening meeting is to allay the fears and apprehensions that the organisation's staff have about the assessment process. The assessment team must make every effort to put the staff at their ease and to ensure that they are fully aware of the assessment objectives and procedures. The team approach and the assurance that non-compliances will be adequately discussed when/if they are encountered, goes a long way towards allaying fears of staff.

This entry meeting need take only about 15-30 minutes to complete. It is appropriate at this stage to seek clarification or additional information relating to the assessment.

Another approach is to ask the organisation's manager to give a brief verbal summary of the work of the organisation and of the business environment in which they work. This can then lead naturally to a discussion of the organisation's briefing information and the resolution of any queries.

Once the assessment process is underway the team should attempt to keep to the agreed timetable, for there is a tendency to spend too long on each topic during the early part of the assessment and a consequent need to rush towards the end.

5.4 Assessment Tactics

Throughout the assessment, team members should be aware of the two main objectives of their visit to the organisation: to determine whether the organisation's operations and facilities comply with the accreditation criteria and if not, to offer advice as to how compliance might be achieved. Assessment team members can adopt a number of tactics to aid in the achievement of these objectives.

5.4.1 Project the Right Image

One of the most valuable tactics for the assessor or expert to employ is to project a professional image of him/herself and of International Accreditation New Zealand as an organisation.

Look the part - a smart tidy appearance creates a favourable impression and boosts self confidence.

Smile and be approachable.

Remain calm and courteous - do not become flustered, emotional, argumentative, or dogmatic. "Please" and "thank you" are amongst the most powerful words in an assessor's vocabulary.

Be precise - loosely phrased questions or requests cause confusion and waste time.

Be prepared - an assessor or expert who has prepared for the assessment projects a professional image.

5.4.2 Conduct of the Assessment

Keep a sense of proportion - every assessment will reveal examples of human error but evidence of fallibility should be of far less interest to the assessment team than evidence of real deficiencies in the organisation's quality management systems. No one appreciates nit-picking!

The magnitude and significance of a deficiency is the vital issue. To pursue every minor error wastes time and alienates the organisation's personnel. Critical comment on minor deficiencies dilutes the effectiveness of critical comment on the major deficiencies.

Assess the true significance of any non-compliance found and avoid making an issue out of trivial deficiencies, human errors or isolated mistakes. However, be alert for apparently minor problems which are, in reality, symptoms of a major system fault.

Keep in mind that if a non-compliance cannot be expressed in terms of the Assessment Criteria (ISO/ IEC 17025, ISO/IEC 17020, or NZS/ISO 15189 Specific Criteria, Supplementary Criteria or Procedures and Conditions of Accreditation, as appropriate, see Section 7), then there is no non-compliance.

If you find no non-compliances after tracing the testing process by a random selection of records and reports, you can reasonably assume that an effective quality management system is in place and is being effectively maintained. If only a few minor non-compliances are found, then the system may be in a development phase or staff may not be fully familiar with the system.

A large number of non-compliances will indicate the absence of an effective system.

Always be fair, flexible and prepared to listen to reason.

Make allowances - consider the circumstances surrounding each non-compliance and do not expect unreasonable levels of diligence or reliability from the organisation's staff.

Be sensitive - put staff at their ease. Do not be afraid to admit that you also make mistakes occasionally.

Be helpful and constructive at all times.

Be factual; verify findings. Beware of producing findings which rely on opinions, whether they be your own or those of the organisation's staff.

Be determined and decisive. Once you have gathered sufficient information to form the basis of a sound judgement, there is no point in going over the same ground again. Move on.

Get on with the job - try not to be sidetracked into irrelevant conversations.

Be aware that in some organisations, ALL staff are prepared and expect to be spoken with during the assessment, while in others non-signatory staff are pleased to be ignored by the assessment team.

Know who's who - be aware at all times of the relationships between staff members. Not only the formal staff structure but also the more important informal structure should be noted.

Bear in mind staff sensitivities and do not criticise staff in front of their subordinates or their seniors.

It is important to discuss problems on the spot - do not just make a note of non-compliance without discussing the matter fully with the auditee. There may be a valid reason for what the organisation is doing.

Be prepared to return - keep returning to an area of the organisation's operations until you are satisfied that compliance with the accreditation criteria exists. Do not be afraid to reassess should you have second thoughts or should another question come to you.

Be aware of the time - as time begins to run short it is better to concentrate on the vital aspects of the organisation's operations.

Avoid too many escorts - it should not be necessary for a large number of staff members to accompany you. A large group slows down the assessment.

5.5 Tactics of the Organisation

It is worth remembering at the time an assessment is being carried out that the majority of the organisation's staff would probably prefer the assessment team not to be there.

Prior to the assessment, and once it is finished, the organisation will probably acknowledge the positive benefits that can arise from such an exercise. On the day of the assessment, however, the staff will be tense and nervous in what can be a very stressful situation. Nobody likes having their work subjected to careful and detailed scrutiny. However, people like talking about their work particularly to Technical Experts.

The following tactics are occasionally adopted by organisational staff, sometimes deliberately but often unwittingly, under stress.

5.5.1 Time Wasting

The waffler - speaks at length but says nothing and never answers the question directly.

The long lunch break - the organisation may arrange to take the assessment team to lunch. If this is at a restaurant some distance away, over two hours can be wasted. A light working lunch at the organisation premises is preferable.

Interruptions - the organisation's staff may be constantly interrupted during the assessment to take phone calls, etc. In such circumstances, ask politely if such calls can be held until the assessment is finished.

Key staff unavailable - the organisation has plenty of notice of the assessment so there should be no reason (other than sickness) for the absence or lateness of key staff members.

5.5.2 'Cook's Tour'

Some organisations present the assessment team with their version of the assessment programme which may include a lengthy tour of the organisation and other areas of interest. Such tours should be politely declined until the assessment is finished.

5.5.3 Pre-selected Documents

The assessment team may be presented with sets of test records and reports for inspection. The assessment team should not waste time by looking at these. Instead, they should select more records and reports of their own choice from the organisation's filing system.

5.5.4 Other Agendas

Sometimes staff in the organisation seek support from the assessment team to help justify new equipment, personnel or facilities, and may even request supportive inclusions in the final assessment report. This is not a function of the assessment team and any such open or overt requests must be resisted with great diplomacy and care. It is essential to stick to the observed factual matters.

6 Information Gathering Techniques

An assessment involves the evaluation of information gathered by the assessment team from a variety of sources including:

- (a) The organisation's accreditation questionnaire and documentation
- (b) Observation of the organisation's practices
- (c) Inspection of the organisation's facilities and records
- (d) Review of proficiency programme results
- (e) Questioning of staff.

6.1 Observation of the Organisation's Practices

Observations of activities of the organisation will provide an insight into the level of competence of the staff and the manner in which the organisation functions.

In some organisations, the assessment team will witness some or all of the tests, measurements or procedures under consideration. This allows them to evaluate the manipulative skills of staff and to detect faults which cannot be established in the questioning process. Even if a particular procedure is too lengthy to be performed in its entirety during the visit, it should be possible for at least the most critical phases of the procedure to be performed in the presence of the assessment team. Depending on the circumstances, samples or specimens or items used in such procedures may be conveniently drawn from the normal work throughput of the organisation or, by arrangement with the International Accreditation New Zealand lead assessor, may be provided by a member of the assessment team.

The Technical Expert is asked to advise the International Accreditation New Zealand lead assessor of any particular test or procedure that he/she would like to see performed during the assessment. This should be done as soon as possible after receipt of the briefing notes, but requests on the day may sometimes be accommodated.

When arranging the assessment, the International Accreditation New Zealand lead assessor will request that, as far as possible, the organisation should continue to function normally throughout the assessment visit. Assessors and experts should recognise that observation of the work going on around the assessment team will often yield just as much information on the real standard of competence and expertise of the testing personnel as the specially arranged witnessed tests or work.

6.2 Inspection of the Organisation's Facilities and Records

Thorough examination of facilities and records is essential to the success of any assessment.

It is particularly important that the records and reporting systems be very carefully and thoroughly examined. Depending upon the volume and variety of work being undertaken in the organisation, the assessment team should select multiple examples of the different types of work being performed and trace through the process from start to finish and sometimes in the reverse direction. These records should be examined for clarity, completeness and consistency. The assessment team should be especially alert to any anomalies or discontinuities; anomalies for which there are no explanation may sometimes be a symptom of a much deeper problem in the operation of an organisation.

6.3 Review of Proficiency Programme Results

Wherever possible, details of any participation by the organisation in external proficiency programmes will be included in the briefing documents for consideration during the assessment.

Opportunity should be taken during the course of the assessment to review with the organisation manager or supervisors the results obtained in these proficiency programmes.

Aspects which should be covered include:

- (a) The acceptability or otherwise of the results obtained in relation to the assigned value or consensus result and the uncertainty of measurement claimed where results are numerical
- (b) How closely the programme instructions were followed
- (c) How closely the proficiency programme approximated the normal operations of the organisation
- (d) Any subsequent investigation undertaken by the organisation to determine the causes of any outlying results
- (e) Whether appropriate effective corrective and preventative actions were taken following outlying results.

6.4 Questioning of Staff

"I keep six honest serving men (they taught me all I knew). Their names are what and why and when and how and where and who." Kipling

Effective questioning of the organisation's staff is vital to the success of any assessment. Questioning must not be aggressive, but it must be thorough and, on occasions respectfully persistent if the real facts are to emerge.

In many situations, it may be desirable for the assessment team to try again to put the organisation's staff at ease at the start of any questioning or interview session. The staff of the organisation will know that they are under investigation and will react in a variety of ways; for example, by becoming withdrawn or defensive or, at the other extreme, by responding aggressively. While these reactions may be due to nothing more than nervousness, they may result in evasive answers which make it more difficult for the assessment team to establish the facts.

Judicious use should be made of both open and closed questions. In general terms, open questions, which require a substantial response, are more useful than closed questions which permit yes/no answers.

For example, it is better to ask: "Tell me about the interferences you have encountered in analysis by this method?" and continue this line of questioning rather than simply ask: "Do you correct for the manganese interference?"

Similarly, it is better to say: "Tell me about your experience in calibration of ..." rather than: "The briefing notes state that you have had five years experience in calibration of..."

Closed questions have a role in the questioning process, but they tend to evoke a defensive reaction in the recipient and may be interpreted as being critical or aggressive. They are best used to clarify particular points during the discussion.

The art of questioning also involves listening for what is not said as much as what is being said. Assessors and Technical Experts should be alert to answers which appear to be superficial or evasive and be prepared to continue the line of questioning if they sense that a response is incomplete. It is often productive to ask "Can you show me ... please?"

The assessment is being undertaken to evaluate the organisation's technical management system which should be able to cope with all situations. Hypothetical questions of the "what if" variety often help in understanding the organisation's systems and in determining whether they can cover all reasonable eventualities. However, the hypothetical scenarios should still be realistic in the context of the organisation's work.

If the organisation's explanation or response is unclear or unsatisfactory, the questioner should not be afraid to admit that he/she does not understand. Keep questioning, rephrasing the question if necessary, until the answer is clear.

When junior staff are being interviewed, there is sometimes a tendency for the senior staff accompanying the assessor or Technical Expert to answer on the junior's behalf. This practice must be tactfully discouraged.

When interviewing, the assessor or Technical Expert should never talk down to the staff member. Such an attitude of superiority is unlikely to elicit co-operation. Speak clearly and carefully, phrasing questions using terminology likely to be understood by the staff member in question. Give credit where it is due. Compliments and the use of “please” and “thank you” are effective in developing communication.

Finally, assessors and Technical Experts should be alert to differences in information presented to them from different sources; for example, conflicting answers from different staff members, or differences between what is said and what is observed. Any such differences should be probed until the true situation is established.

6.5 Six Task Elements

In assessing an organisation’s operations and facilities, each activity or task can be considered in terms of six elements. These so called task elements are:

- (a) The person who performs the task
- (b) The items on which the task is performed and any consumables used
- (c) The equipment and facilities used in performing the task
- (d) The procedure or method used in performing the task
- (e) The records and reporting associated with the task
- (f) Quality control.

In evaluating an organisation’s operations, assessors and Technical Experts should keep these six task elements in mind and ask themselves the following questions:

6.5.1 The Person

Are the people competent to perform the task?

Are they appropriately qualified and experienced?

Do they have the necessary manual skills?

Are they suitably motivated to undertake the task in a conscientious, diligent and reliable manner?

Are they identified in the training records as the ones who are appropriately trained?

6.5.2 The Items and Consumables

Is the item being worked upon (sample, patient, object, instrument for calibration, etc) of the correct type, in the correct condition, suitably identified?

Are consumables of suitable quality and certified/guaranteed where required?

6.5.3 The Equipment

Are test equipment and other facilities (e.g. organisation, accommodation, and environment) appropriate to the task?

Are necessary standards available and current?

Is test equipment suitably calibrated; does it comply with the requirements of the organisation’s nominated procedures?

Is equipment well maintained and housed? Is it suitably identified?

6.5.4 The Procedure or Method

Is the method or the procedure appropriate to the task?

Is it a current procedure?

Are standard specifications available?

Is the method within the organisation's capabilities?

Is the documented method being followed?

6.5.5 Records and Reporting

Are the records associated with the task available and appropriate for that task?

Do test records and reports, etc comply with the accreditation criteria for such records?

Are all records appropriately stored and retrievable?

6.5.6 Quality Control

Is there a quality control plan?

Are calculations and information/data transfers and reports checked?

Is some work repeated to establish repeatability?

Are known artefacts or materials tested or inspected?

Are there appropriate and sufficient work comparisons with other organisations (proficiency testing)?

Are there action criteria for when QC results are unacceptable?

Are there trend charts or other statistical means of analysing QC results?

A task element analysis can be applied to all aspects of the organisation's work, from reception of work to the typing of a report.

Each task in the chain must be performed correctly if the organisation's product, its report, is to be of a suitable quality i.e. fit for the purpose to which it will be put.

7 Criteria for Accreditation

The formal criteria for accreditation include the following publications:

7.1 General Criteria Documents

NZS ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

Requirements for Inspection Body Accreditation in New Zealand incorporating AS/NZS ISO/IEC 17020 and interpretations.

NZS/ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence

New Zealand Code of Radiology Management Practice

These documents include:

- (a) Management system requirements to be assessed mainly by the IANZ lead assessor
- (b) Technical requirements to be assessed mainly by the Technical Expert.

7.2 Specific Criteria Documents (published by International Accreditation New Zealand)

Additional technical requirements (to be assessed mainly by the Technical Expert).

Signatory or Key Technical Personnel requirements (to be assessed mainly by the Technical Expert).

7.3 Supplementary Criteria Documents (published by International Accreditation New Zealand)

Additional technical requirements (to be assessed mainly by the Technical Expert).

7.4 Procedures and Conditions of Accreditation

Conditions of accreditation.

International Accreditation New Zealand rules for endorsing reports.

Copies of the above criteria have been supplied for reference to all Technical Assessors.

8 Confidentiality

All information provided by an organisation in relation to its accreditation and all information obtained in the course of or in connection with an assessment must be treated with the strictest confidence. Even the fact that a particular organisation has applied for accreditation or has been assessed is regarded as being confidential.

Assessors, Technical Experts, Advisory Committee members and Council are required to sign Confidentiality Agreements before any involvement in the assessment or the granting of accreditation. The agreement includes an endorsement that there is no conflict of interest between the assessor or Technical Expert, etc and the organisation to be assessed. Assessors and Technical Experts are asked not to discuss any matters relating to an assessment with any person other than those assessee staff members directly involved in the assessment and International Accreditation New Zealand staff.

A technical matter may arise during an assessment upon which an assessor may wish to undertake some research or seek advice before formulating final recommendations. As far as is possible, such investigations should be undertaken in a manner that will maintain International Accreditation New Zealand's principles of confidentiality.

The Council also requires that all documents associated with accreditation of an organisation be maintained in strict confidence. This requirement imposes particular obligations on assessors and Technical Experts. All the briefing notes, assessor notes, etc, are to be returned to the International Accreditation New Zealand lead assessor at the end of the assessment.

International Accreditation New Zealand then includes in its file all the Technical Expert's notes, etc, from the assessment and will return a copy should it be necessary for the Technical Expert to refer to them later during clearance of any conditions from the assessment.

9 Bibliography

Laboratory Assessor Guide, National Association of Testing Authorities of Australia, 1992.

Management Audits, Allan J Sayle, McGraw Hill Book Company (UK) Ltd 1981.

NZS ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*.

Assessor Guidelines

NZS/ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence, IANZ AS MT C.

New Zealand Code of Radiology Management Practice, IANZ AS RAD C.

Requirements for Inspection Body Accreditation in New Zealand incorporating AS/NZS ISO/IEC 17020 and interpretations IANZ AS IB C.

ISO 10011 Guidelines for Auditing Quality Systems.