

IMPLEMENTING NZS/ISO/IEC 17025:2005

Background

International Accreditation New Zealand (IANZ) currently uses the international and New Zealand standard NZS/ISO/IEC 17025:1999 as generic accreditation criteria for all laboratories except medical testing laboratories (the latter being accredited against the NZS/ISO 15189:2003).

The international standard ISO/IEC 17025:1999 has for some years been undergoing a revision to align it with ISO 9001:2000. This review is now complete and the International Organisation for Standardisation (ISO) published, on 15 May 2005, the 2005 edition ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*.

The following summarises the changes and up-dates in the new edition and details the transition requirements for accredited laboratories (except medical testing laboratories) to implement the new standard.

ISO 9001:2000 & ISO/IEC 17025:2005

From its origins in ISO/IEC Guide 25:1990, ISO/IEC 17025:1999 was created and documented to harmonise with ISO 9001:1994. Soon after its publication and implementation, ISO 9001:2000 was released and it could no longer be claimed that the management system's aspects of ISO/IEC 17025:1999 met the requirements of ISO 9001:2000. The revision of ISO/IEC 17025:1999 was embarked upon to correct this alignment.

With ISO/IEC 17025:2005, accredited laboratories will be able to state that the management system requirements of ISO/IEC 17025:2005 (Section 4) are written in a language relevant to and meeting the principles of ISO 9001:2000 and are aligned with its pertinent requirements - a position formally recognised by ISO.

This is reflected in Clause 1.6 of ISO/IEC 17025:2005, which previously (1999 edition) stated that laboratories complying with ISO/IEC 17025:1999 would "also meet the requirements of ISO 9001" Clause 1.6 now states that laboratories that comply with ISO/IEC 17025:2005 meet the "principles of ISO 9001".

While accreditation to ISO/IEC 17025:2005 does not infer full conformity with ISO 9001:2000, ISO, International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) have released a joint communiqué (copy

available from IANZ on request) that will give those testing and/or calibration laboratories that are ISO/IEC 17025:2005 accredited an official attestation on their management system to provide to their customers that are requiring ISO 9001:2000 certification.

New Zealand Adoption

IANZ has arranged with Standards New Zealand to have ISO/IEC 17025:2005 adopted as a New Zealand Standard, and has published and printed the new standard, NZS/ISO/IEC 17025:2005, on behalf of IANZ. A copy of this new accreditation standard is being made available free of charge to all accredited and applicant laboratories. Additional copies can be obtained from IANZ on request, but a nominal charge may apply for each additional copy.

New and Updated Requirements

Both ISO and ILAC recognise that the changes and up-dates are not substantial and should have only minimal impact on the operation of accredited laboratories in terms of their conformity with the ISO/IEC 17025:2005 accreditation standard.

The added and amended clauses deal primarily with how laboratory management ensure effective communication and how the effectiveness of the management system is continually improved. This is reflected in the majority of changes being in the Management Requirements section (Section 4) of the standard. There are also some additions to the Technical Requirements (Section 5). All the new requirements are included in the attached **NZS/ISO/IEC 17025:2005 Implementation Table**, which details the changes and gives guidance from IANZ on the expectations on laboratories in terms of implementation of these requirements.

Terminology

Throughout NZS/ISO/IEC 17025:2005 (but not included in the detail of the Implementation Table), any references to "quality system", "client", and "conformance" have been replaced by "management system", "customer", and "conformity" respectively.

These subtle changes in terminology to align with current ISO conventions are not expected to be changed immediately in the documentation of your existing quality (management) system. These changes in wording should be addressed as the relevant procedures are reviewed and up-dated as part of your laboratory's routine review process.

Transition

ILAC has confirmed a transition period of two years for the implementation of ISO/IEC 17025:2005. As a signatory to the ILAC Mutual Recognition Arrangement, IANZ and its accredited laboratories are bound by this transition period.

Therefore, all accredited laboratories (except medical testing laboratories) must demonstrate their conformity with the new standard by 1 June 2007.

Given that the changes and up-dates in the new standard are not considered substantial, **IANZ assessment teams will commence assessment of laboratories against the requirements of the new standard from 1 February 2006.**

This applies to both currently accredited laboratories at their next scheduled annual surveillance visit or routine reassessment after 1 February 2006 and applicant laboratories at their initial assessment.

Accredited laboratories will be given the usual period (generally three months) to clear any Corrective Action Requests from the Assessment Report that relate to the implementation of the new requirements. Longer periods may be negotiated on a case-by-case basis in exceptional circumstances, but laboratories are reminded that all accredited laboratories must demonstrate conformity by the 1 June 2007 deadline.

Once conformity has been demonstrated, IANZ will issue new Certificates of Accreditation and new Schedules to the Certificate of Accreditation detailing the new accreditation standard.

Further Information

If you have any queries regarding the implementation of the 2005 edition of NZS/ISO/IEC 17025 please do not hesitate to contact the IANZ General Manager Accreditation Services or your relevant IANZ Programme Manager.

NZS/ISO/IEC 17025:2005 Implementation Table

Clause No. & Title	Amended/ New	Extract of NZS/ISO/IEC 17025:2005	IANZ comment
Section 4: Management Requirements			
4.1.5(a) Organisation	Amended	<p>The laboratory shall have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties.</p> <p>These include the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2)</p>	<p>There should be no effective change from the existing application of the standard. These personnel should be identified [clause 4.1.5(f)], including those responsible for the implementation, maintenance and improvement of the system.</p>
4.1.5(k) Organisation	New	<p>The laboratory shall ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.</p>	<p>This new clause is centred on the need for laboratory management to communicate to their staff the overall objectives of the organisation and how individuals contribute to achieving these.</p> <p>All levels of staff may be interviewed by assessment teams in order gauge the effectiveness of this communication and the understanding of the messages conveyed.</p>

4.2.7 Management System	New	Top management shall ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.	<p>Changes to the management system, whether major or minor, are always expected to be reflected in amendments to the documentation of the system.</p> <p>Reviews of such amendments should be undertaken by appropriate staff who are able to assess the impact of the changes on the integrity of the overall system.</p> <p>Management reviews and corrective action processes will also need to ensure that any decisions made do not have any adverse effect on the operation of other areas of the management system.</p>
4.7.1 Service to the Customer	Amended	The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.	No expected change to the existing application of the standard.
4.7.2 Service to the Customer	New	<p>The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.</p> <p><i>Note: Examples of this type of feedback include customer satisfaction surveys and review of test or calibration reports with customers.</i></p>	<p>The Note provides examples only and are not mandatory. Other mechanisms may be general solicitations sent out with test reports; via the laboratory website; informal chats with internal customers; and/or the like.</p> <p>It is important that in order to be compliant with this clause, laboratories must maintain records of this feedback as well as records of the manner in which this feedback is used.</p>
4.10 Improvement	New	The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	Continual improvement (an overall improvement over time, but may include backward steps from time to time) is not the same as continuous improvement (one step always an improvement on the last). The indicators or measures of the management system effectiveness will need to show a continual improvement.
4.11 Corrective action	Renumbered only from 4.10 (1999)		
4.12 Preventive action	Renumbered only from 4.11 (1999)		
4.13 Control of records	Renumbered only from 4.12 (1999)		
4.14 Internal audits	Renumbered only from 4.13 (1999)		
4.15.1 Management reviews	Amended and renumbered from 4.14 (1999)	The list of items to be covered has been expanded to include recommendations for improvement.	Recommendations for improvement would be expected to be inherent in the laboratory's objectives for continual improvement of the management system and their review at management reviews.

Section 5: Technical Requirements

<p>5.2.2 Personnel</p>	<p>Amended</p>	<p>The effectiveness of the training actions taken shall be evaluated.</p>	<p>This applies to particular training events undertaken by individuals, rather than the overall training programme as a whole.</p> <p>The training undertaken should be revisited after the event to make an assessment of whether the objectives of the training had been met. Laboratories may already be making such evaluations to varying degrees of formality, but now records need to be maintained of these reviews.</p>
<p>5.9.2 Assuring the quality of test and calibration results</p>	<p>New</p>	<p>Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.</p>	<p>For many laboratories, this requirement has already been part of the accreditation criteria and an integral part of their preventive action programmes.</p> <p>Laboratories will be expected to establish their pre-defined criteria in a transparent (documented) and technically valid manner, and to define what processes are to be followed where these limits are exceeded – normally calling up the control of non-conforming test and/or calibration work (clause 4.9) and corrective action (clause 4.11) procedures.</p>