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NATA POLICY CIRCULAR
June 2005

National Association of Testing Authorities, Australia

Implementation Of ISO/IEC 17025:2005

1. Background

ISO/IEC 17025:1999 has for some years been undergoing a revision in order to align it with ISO 9001:2000. As a result of this review ISO/IEC 17025:2005 was published on 15 May 2005. The International Laboratory Accreditation Cooperation (ILAC) has adopted a two year implementation period for this new version of ISO/IEC 17025. This means that all facilities accredited to this standard must comply with the 2005 version by 15 May 2007. The adoption of this standard as an Australian Standard is yet to be formalised by Standards Australia, and hence it has not yet been published as an Australian Standard.

In order to meet our ILAC commitment to ensure all accredited facilities comply with the new version of the Standard by the set time, we have decided to begin assessing against the 2005 version from 1 July 2005. To enable facilities to address the additional requirements now, these have been included in the attached ISO/IEC 17025:2005 Implementation Table. When the Australian version of ISO/IEC 17025 is published by Standards Australia we will advise all Authorised Representatives of the most practical and cost effective means of purchasing a copy.

2. New Requirements

As advised in several issues of NATA News over the past 18 months, the changes are largely in Part 4 Management Requirements since the purpose of the amendment was alignment with ISO 9001:2000, a quality management standard. There are however also some additions to Part 5 Technical Requirements.

All the new requirements are included in the attached table **ISO/IEC 17025:2005 Implementation Table** and compliance with the requirements will be mandatory from 1 July 2005.

A copy of this table will be forwarded as part of the preparation for your next assessment visit. We will be asking that you provide the relevant document references to where the new requirements are covered in your system.

3. Terminology

Throughout the Standard, any references to "quality system", "client "and "conformance", have been changed to "management system", "customer" and "conformity" respectively. It is not expected that the documentation in your existing quality (management) system be changed to reflect to this wording. These changes in wording should however be addressed as the relevant procedures are reviewed and updated as part of the facility's review process.

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Distribution

All Authorised Representatives
Available at Website

NATA is Australia's national laboratory accreditation system. Established in 1947, it is the largest association of laboratories in the world and serves as the model for many overseas accreditation systems. NATA accredits laboratories in sixteen different fields of testing covering areas such as engineering, pathology, construction, applied physics, chemistry, biology, forensic, veterinary, non-destructive testing and metrology. NATA also offers accreditation for Medical Imaging facilities.

Amendment History

Issued: June 2005

4. Reference to ISO 9001:2000

Clause 1.6 previously stated that laboratories complying with ISO/IEC 17025 would "also meet the requirements of ISO 9001…". The clause now states that laboratories that comply with ISO/IEC 17025 meet the "principles of ISO 9001." ILAC are still in the process of negotiating a statement that can be used by accredited facilities in relation to this issue. We will advise all Authorised Representatives when this statement has been finalised.

5. Assessment Process from 1 July 2005

All assessments of facilities currently accredited to ISO/IEC 17025:1999 will be conducted to ISO/IEC 17025:2005. This includes all reassessments and variations.

Applicant facilities: All initial assessments (regardless of the date of application) will be assessed against ISO/IEC 17025:2005.

Coding: Any non-compliances to the new requirements will be coded as Cs (conditions) and will need to be closed out in the time frame agreed during the exit meeting.

Scope of Accreditation: When all the requirements for accreditation have been met, the scope of accreditation for the facility will be updated to include reference to the latest version of the Standard. Please note the new format for the NATA accreditation certificates, (ie with the new logo), does not include reference to the version (year) of the accreditation standard, as this information is included on the scope of accreditation.

Paperwork: The Laboratory Assessment Worksheet (LAW) available from the web site, has been updated to include the new requirements. These are included in bold for easy identification.

6. Queries

If you have any queries regarding the implementation of the 2005 version of ISO/IEC 17025 please contact the relevant field manager.

ISO/IEC 17025:2005 Implementation Table

Clause Nº	Amended/New	Extract of ISO/IEC 17025:2005
Part 4 Management Requirements		
Clause 4.1.5(k)	New	"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."
Clause 4.1.6	New	"Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system."
Clause 4.2.2	Amended	"The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following: c) the purpose of the management system related to quality e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system."
Clause 4.2.3	New	"Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness."
Clause 4.2.4	New	"Top management shall communicate to the organisation the importance of meeting customer requirements as well as statutory and regulatory requirements."
Clause 4.2.5	4.2.3 (1999) renumbered only	
Clause 4.2.6	4.2.4 (1999) renumbered only	
Clause 4.2.7	New	"Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented."
Clause 4.7.1	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."
Clause 4.7.2	New	"The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service. *Note: Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers."*

ISO/IEC 17025:2005 Implementation Table

Clause Nº	Amended/New	Extract of ISO/IEC 17025:2005
Clause 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."
Clause 4.11 Corrective action	Renumbered from 4.10 (1999) only	
Clause 4.12 Preventive action	Renumbered from 4.11 (1999) only	
Clause 4.13 Control of records	Renumbered from 4.12 (1999) only	
Clause 4.14 Internal audits	Renumbered from 4.13 (1999) only	
Clause 4.15 Management reviews	Amended and renumbered from 4.14 (1999)	The list of matters to be covered has been expanded to include "recommendations for improvement" as required by the new clause 4.10 Improvement and 4.12 Preventive action.
Part 5 Technical Requirements		
Clause 5.2.2	Amended	The following additional requirement has been added: "The effectiveness of the training actions taken shall be evaluated."
Clause 5.9.2	New	"Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported."