Specific Accreditation Criteria

ISO/IEC 17025 and ISO 15189 Application Document

Legal - Annex

Policy for the transition of medico-legal drug testing accreditation from ISO 15189 to ISO/IEC 17025

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Section 1: Policy for the transition of medico-legal drug testing accreditation from ISO 15189 to ISO/IEC 17025

Purpose

This policy is effective from 1 October 2020 and describes changes to the *NATA Accreditation Criteria* (NAC) applicable to all facilities performing medico-legal drug testing currently accredited to ISO 15189 *Medical laboratories - Requirements for quality and competence* or have a pending application for the accreditation of medico-legal drug testing.

Background information

Following engagement with accredited facilities and feedback received, a decision has been made to transition, from October 2020, the accreditation of facilities who offer such testing as a standalone activity to *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*.

Transition will not be applicable to pathology laboratories who also offer medico-legal drug testing performed as an integral part of their overall pathology services. However, pathology laboratories may wish to have such testing transitioned to ISO/IEC 17025 upon request.

The rationale for the transition is that medico-legal drug testing is not considered a clinical / diagnostic service and hence, ISO/IEC 17025 is the most appropriate standard to accredit the activity. Further, the Therapeutic Goods Administration (TGA) has determined that such testing does not constitute an In-Vitro Diagnostic device (IVD) subject to the TGA IVD regulations.

Note: ISO 15189 defines a medical laboratory as:

> *A laboratory for the biological, immunological, chemical, immunohaematological, haematological, biophysical, cytological genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.*

Assessment of facilities to ISO/IEC 17025

As described in the *NATA Procedures for Accreditation*, facilities must obtain a copy of the standard for which accreditation is held or being sought. Accordingly, facilities must purchase a copy of ISO/IEC 17025:2017 (either from a supplier of ISO or Australian standards).

A copy of the relevant documents in the Legal (including Forensic Science) *NATA Accreditation Criteria* package must also be obtained from the NATA website (https://www.nata.com.au/accreditation-information/accreditation-criteria-and-guidance/nata-accreditation-criteria-nac-packages/laboratory-accreditation-iso-iec-17025/category/20-legal).

Applicant facilities

Applicant facilities will be assessed against ISO/IEC 17025 if they have not yet had an assessment conducted by 1 October 2020. If an assessment has already occurred against ISO 15189, then a desk-top review, as described below, will be conducted prior to the granting of accreditation against ISO/IEC 17025.

Accredited facilities

The changes between ISO 15189 and ISO/IEC 17025 are such that some assessment will be necessary to transition accreditation.

Assessment by NATA will be by desk-top review of information and documentation submitted by the facility.

All facilities offering medico-legal drug testing as standalone activity will be contacted in October 2020 to request the information and documentation to be submitted within a four week period.

As of 1 August 2021, medicolegal drug testing accredited under ISO 15189 will be withdrawn from the scope of accreditation unless the organisation offer medico-legal drug testing as an integral part of their overall pathology services.

To assist facilities, a *Correlation Table* between ISO 15189:2012 and ISO/IEC 17025:2017 has been prepared and included in Section 2 of this policy document.

The desk-top assessment will include:

- confirmation the facility has obtained a copy of ISO/IEC 17025:2017 and the relevant documents included in the Legal *NATA Accreditation Criteria* package;
- review of the completed and returned *Implementation Checklist*: *Transition of Medico-Legal Drug Testing Accreditation from ISO 15189 to ISO/IEC 17025* together with any supporting documentation relating to changes adopted by the facility to comply with the standard. A copy of the *Implementation Checklist* is included in Section 3 of this policy document.

The facility's accreditation will be transitioned to ISO/IEC 17025 should no significant issues be identified during the desk-top review. Where additional information is required, these will be requested by NATA prior to further consideration being given to transitioning the accreditation.

Once accredited to ISO/IEC 17025, facilities will be placed on the 3 year assessment cycle as described in the *NATA Procedures for Accreditation*. The scope of accreditation will also be updated to reference the standard and a new accreditation certificate will be issued.

No fees will be charged for transitioning to ISO/IEC 17025 and annual NATA fees will remain unaffected.

Further information

Further information can be obtained by contacting your NATA Client Coordinator.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO 15189 *Medical laboratories - Requirements for quality and competence*

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

NATA Publications

Legal (including Forensic Science) *NATA Accreditation Criteria* package

NATA Procedures for accreditation

Amendment table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Accredited facilities	Deadline for transition now included.

Section 2: Correlation table - ISO/IEC 17025:2017 and ISO 15189:2012

ISO/IEC17025:2017 Clause Number		ISO 15189:2012 Clause Number	
1	**Scope**	**1**	**Scope**
2	**Normative references**	**2**	**Normative references**
3	**Terms and definitions**	**3**	**Terms and definitions**
4	**General requirements**	**4**	**Management requirements**
4.1	Impartiality	4.1	Organisation and management responsibility
4.2	Confidentiality	4.1	Organisation and management responsibility
5	**Structural requirements**	4.1	Organisation and management responsibility
		4.7	Advisory services
6	**Resource requirements**		
6.1	General	4.1	Organisation and management responsibility
6.2	Personnel	5.1	Personnel
6.3	Facilities and environmental conditions	5.2	Accommodation and environmental conditions
6.4	Equipment	5.3	Laboratory equipment, reagents and consumables
6.5	Metrological traceability	5.3.1.4	Equipment calibration and metrological traceability
6.6	Externally provided products and services	4.6 4.5	External services and supplies Examination by referral laboratories
7	**Process requirements**		
7.1	Review of requests, tenders and contracts	4.4	Service agreements
7.2	Selection verification and validation of methods	5.5	Examination processes
7.3	Sampling	5.4	Pre-examination processes

ISO/IEC17025:2017 Clause Number		ISO 15189:2012 Clause Number	
7.4	Handling of test or calibration items	5.4 5.5 5.8	Pre-examination processes Examination processes Reporting the result
7.5	Technical records	4.13	Control of records
7.6	Evaluation of measurement uncertainty	5.5	Examination processes
7.7	Ensuring the validity of results	5.6	Ensuring the quality of examination results
7.8	Reporting the result	5.7 5.8 5.9	Post examination processes Reporting the result Release of results
7.9	Complaints	4.8	Resolution of complaints
7.10	Nonconforming work	4.9	Identification and control of nonconformities
7.11	Control of data and information management	5.5 5.10	Examination processes Laboratory information management
8	**Management system requirements**	**4**	**Management requirements**
8.1	Options		
8.2	Management system documentation (Option A)	4.2	Quality management system
8.3	Control of management system documents (Option A)	4.3	Document control
8.4	Control of records (Option A)	4.13	Control of records
8.5	Actions to address risks and opportunities (Option A)	4.11 4.12 4.14	Preventive action Continual improvement Evaluation and audit
8.6	Improvement (Option A)	4.12	Continual improvement
8.7	Corrective actions (Option A)	4.10	Corrective action
8.8	Internal audits (Option A)	4.14	Evaluation and audit
8.9	Management review (Option A)	4.15	Management review
Annex A (informative) Metrological Traceability			
Annex B (informative) Management system options			

Section 3: Implementation Checklist: Transition of medico-legal drug testing accreditation from ISO 15189 to ISO/IEC 17025

This checklist is to be completed and returned to NATA.

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary) (Attach supporting evidence separately and include reference to the clause number)**
4.1.4	Expanded requirement	On an ongoing basis, the laboratory must identify risks to impartiality, including those arising from its activities or relationships or the relationships of its personnel.	
4.1.5	Expanded requirement	The laboratory must be able to demonstrate how it minimises or eliminates any risks to impartiality that it identifies.	
4.2.1	New requirement	The laboratory is responsible, through legally enforceable commitments, for the management of information obtained or created during its activities. If the laboratory intends to place information in the public domain, it must inform the customer in advance. Unless agreed between the laboratory and customer or the customer makes the information publicly available, all other information is to be regarded proprietary and confidential.	

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
4.2.2	New requirement	When the laboratory is required by law or authorised by contractual arrangements to release otherwise confidential information, the customer or individual is to be notified (unless the notification is prohibited by law).	
4.2.3	New requirement	Information about the customer, obtained from other sources, is to be regarded as confidential. The source is to remain confidential to the customer unless otherwise agreed to by the source.	
4.2.4	New requirement	Personnel must keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.	
5.3	New requirement	The laboratory needs to define and document the range of activities which it claims conformity to the Standard. The range of activities cannot include externally provided laboratory activities on an ongoing basis.	
6.2.5	Expanded requirement	Procedures and records must be maintained for personnel covering: a) determination of competence requirements; b) to e) selection, training, supervision and authorisation; and f) monitoring of competence.	

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
6.2.6	Expanded requirement	Personnel must be authorised to perform specific activities including: a) develop, modify, verify and validate methods; b) analysis of results, statements of conformity and opinions / interpretations; c) report, review and authorise results.	
7.1.3	New requirement	The standard or specification and the decision rule must be clearly defined when the customer requests a statement of conformity to a specification or standard for a test or calibration. The decision rule must be communicated to and agreed with the customer, unless inherent in the requested specification of standard.	
7.8.2.2	New requirement	The laboratory is responsible for all the information in the report, except that provided by the customer. Data provided by the customer is to be clearly identified. Additionally, a disclaimer must be included when information is supplied by the customer which can affect the validity of the results. When the laboratory is not responsible for sampling, e.g. the sample has been supplied by the customer, it must state in the report that the results apply to the sample as received.	

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
7.8.6.1	New requirement	When a statement of conformity to a specification or standard is provided, the laboratory must document the decision rule it employs, taking into account the level of risk associated with the decision rule, and apply the decision rule.	
7.8.6.2	New requirement	The laboratory must report on the statement of conformity: a) the results to which the statement of conformity applies; b) which specifications, standards or parts thereof that are met or not met; c) the decision rule applied (unless inherent in the requested specification or standard).	
7.9.2	Expanded requirement	A description of the complaint handling process must be available to any interested party on request. Upon receiving a complaint, the laboratory must determine if it relates to the laboratory activities it is responsible for and if so, needs to deal with the complaint. The laboratory is responsible for all decisions in handling the complaint.	

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
7.9.3	Expanded requirement	The complaints handling process must include: a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions taken to resolve them; c) ensuring that any appropriate action is taken.	
7.9.4	Expanded requirement	The laboratory receiving the complaint is responsible for gathering and verifying all information to validate the complaint.	
7.9.5	Expanded requirement	Whenever possible, the laboratory must acknowledge receipt of the complaint and provide the complainant progress reports and the outcome.	
7.9.6	Expanded requirement	The outcomes are to be communicated to the complainant by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.	
7.9.7	Expanded requirement	Whenever possible, the laboratory is to give formal notice of the end of the complaint handling to the complainant.	

ISO/IEC 17025:2017 Clause No.	**Emphasis of change compared to ISO 15189**	**Summary of text/extract from ISO/IEC 17025:2017**	**Action taken with reference to supporting evidence (as necessary)** **(Attach supporting evidence separately and include reference to the clause number)**
8.1.3	New requirement	Only applicable if Option B is adopted. A laboratory that maintains a management system, in accordance with the requirements of ISO 9001 which supports and demonstrates the consistent fulfilment of clauses 4 to 7, fulfils the intent of the management system requirements of 8.2 to 8.9.	Refer to *General Accreditation Criteria: ISO/IEC 17025 Standard Application Document.*
8.5.3	New requirement	Only applicable if Option A is adopted. Actions taken to address risks and opportunities need to be proportional to the potential impact on the validity of the laboratory results.	Refer to *General Accreditation Criteria: ISO/IEC 17025 Standard Application Document.*
8.9.2	New requirement	Only applicable if Option A is adopted. Inputs to the management review are to be recorded and also include information related to: a) changes in internal and external issues that are relevant to the laboratory; b) fulfilment of objectives; l) adequacy of resources;	Refer to *General Accreditation Criteria: ISO/IEC 17025 Standard Application Document.*