AS 4760

Procedures for Specimen collection and the detection and quantitation of drugs in oral fluid

Standards Australia Workshop

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Introduction

• In this presentation we will cover –
  • Who are NATA, what does NATA do?
  • What NATA does not do
  • Issues identified
Who are NATA? What do we do?

• Established in 1947 by the Commonwealth Government

• Recognised in an MOU with the Commonwealth Government as the National Accreditation Body for the accreditation of
  • laboratories
  • inspection bodies
  • calibration services
  • producers of certified reference materials
  • proficiency testing scheme providers

• Authority in the assurance of technical standards

• Utilise thousands of technical experts who volunteer their time in evaluating the technical competence of laboratories – the peer review process

• NATA is
  • government-endorsed
  • independent
  • not-for-profit company
  • guided and monitored by a Board of Directors
The peer review accreditation process:

- ensures compliance with relevant International and Australian standards
  - **ISO/IEC 17025, ISO 15189**
    - Conformity Assessment Standards
  - **AS/NZS 4308, AS 4760**
    - Standard methods
    - Facilities are not Accredited to a Standard method alone but must also meet one of the CAS above
  - ensures facilities are competent to provide consistently reliable testing, calibration, measurement and inspection data to government, industry and the wider community
- Is a signatory to ILAC / APLAC MRAs
  - facilitates / promotes recognition of results in other economies whose accreditation bodies are signatory to the MRAs
The peer review accreditation process:

- Reviews all aspects of a facilities operations in terms of **technical competence** and covers the entire test cycle

  - **Pre-analytical phase**
    - Request generation
    - Sample collection
    - Specimen receipt and reception etc

  - **Analytical phase**

  - **Post analytical phase**
    - Reporting of results
    - Interpretations & comments
    - Sample and records retention

- An integral part of the accreditation process is a review the Quality Management System and its governance of laboratory operations

- Reviews the competence of Staff in performing assigned tasks
Therefore Accreditation is not simply

• “Do you have a procedure for given method or test”

But also includes

• Does the procedure meet the needs of the client in terms of technical criteria;
• Is the method appropriately validated and controlled;
• Are staff trained and deemed competent in the procedure;
• Is the sample used traceable back to its source throughout the testing process
• Are there acceptance/rejection criteria available for the sample
• What is the ongoing performance of the method as performed by the facility
• Is the performance acceptable for the testing undertaken
• Is the result reported clearly and unambiguously
• Are any interpretations or comments technically and/or clinically valid
Certification vs Accreditation

**Certification** (ISO 9000 series)

covers an organisation’s **management system**

*does not confirm technical competence*

**Accreditation** (ISO/IEC 17025 / ISO 15189)

confirms technical competence **and** covers an organisation’s management system (principles of ISO 9001)

**Accreditation** assessments are conducted by a quality systems expert **plus** practicing, **technical expert(s)**

**Certification** assessments rarely include both
What NATA does **not do**

- NATA does not perform testing

- NATA is not responsible for writing Standards or setting technical criteria
  - This is performed by recognised standards writing bodies such as Standards Australia and ISO

- NATA does not comment on the technical content of Standards
  - This is for the technical experts on drafting committees to do

- But NATA will comment on the use of Standards from our experiences on accreditation
  - what works and what doesn’t
What NATA does not do

- NATA does not comment on what testing a facility should perform or if one form of testing is “better” than another
  - Urine vs Oral Drug testing
- NATA does not perform product certification or product approval
  - “Does my device meet AS 4760 or AS/NZS 4308”
  - “Can you tell me which devices are “approved” for use?”
- Does not recommend the use of one method, device or manufacturer over another
  - “Can NATA suggest a device I can use for Drug testing ?”
- Does not recommend the use of one accredited facility over another
  - “Can NATA suggest the best provider for me to use ?”
What NATA does **not do**

- NATA does not provide training to meet standard requirements
  - i.e. Collector training
- NATA does not approve training courses
- NATA does not “approve” personnel
  - “I want to employ Mrs Smith, can NATA approve me to employ them?”
- Although if a Standard requires certain qualifications or experience NATA will assess the designated staff against these criteria
- Although meeting a Standard or regulatory requirement is only part of the process – personnel also need to be technically competent
- NATA cannot provide a consultancy service
Resources

www.nata.com.au

2. Information paper 10 – Workplace drug Testing – A guide to Industry
AS 4760 Accredited facilities

Section 2 – Collection, Storage, Handling and Dispatch
14 facilities

Section 3 – On-site initial testing
0 accreditations (no facility has ever been accredited to S3)

Section 4 – Laboratory initial testing
5 facilities

Section 5 – Confirmatory testing
10 facilities
AS 4760 Section 3 – On-site initial testing

NATA sent a communiqué to Authorised Representatives in July 2013

This communiqué advised of the decision to withdraw the provision of accreditation for this testing

NATA were unable to provide a consistent and timely assessment of Section 3 of AS4760: 2006

NATA was unable to make definitive decisions with regard to the granting of accreditation – created uncertainty

This situation was not in the best interests of facilities seeking accreditation or their customers

NATA resolved to remove the continued uncertainty around on site screening until such time as the issues can be resolved

Until further notice NATA will no longer accept applications for accreditation and any current applications will no longer be progressed
A summary of the issues identified in relation to this testing include:

- There are no clearly defined cut-offs concentrations for devices published in AS 4760:2006 as there are for urine devices in AS/NZS 4308:2008;

- The target concentrations for screening devices are described as nominated concentrations

- The standard also states that
  
  - “there is yet to be an accepted cut-off concentration”

  - “Concentrations higher than the initial testing target concentrations may sometimes be used if sensitivity is the limiting factor but this reduces the ability to detect drug use”
Thus a facility may nominate its own target so long as the concentration is not below those in Table 5

- This may result in inconsistent detection rates depending on the nominated cut-off
- The allowance for nominated screening concentrations at levels at the confirmatory concentrations may impact on the ability of confirmatory testing to reproduce a non-negative result due to loss of drug during transport
• There is no definitive criteria for what constitutes “fit for purpose” as described in AS 4760:2006 Section 1.6.1;

• There is no defined protocol for device verification such as is available for urine devices in AS/NZS 4308:2008 Appendix B;

• There is no acceptance criteria for what constitutes acceptable verification of devices as published in Appendix B of AS/NZS 4308:2008;
• The below cut-off Internal QC is defined as a drug free negative specimen.

  • This does not test the sensitivity of devices to identify or not specimens which contain drugs at a concentration below the nominated target cut-off.

  • This is inconsistent with AS/NZS 4308:2008 Appendix A which requires a below cut-off QC at a concentration between 25% and 50% below the cut-off concentration;

• The Positive control is 50% above the nominated concentration

  • This is inconsistent with AS/NZS 4308:2008 which requires the positive control to be between 25% and 50% of the cut-off concentrations (in Table 1)
Summary

Should the above issues be resolved, NATA will reconsider providing accreditation for Section 3 of AS 4760:2006.

To date, no organisation has achieved accreditation to Section 3.

The decision does NOT affect the provision of accreditation for Sections 2, 4 or 5 of AS 4760:2006.

The NATA decision does not imply that:

- the performance of Oral Fluid devices is suspect
- employers should not use Oral Fluid as part of their testing regime
- urine is the preferred option
- the technical competence of testing agencies should be questioned
Thank you