

# **Specific Accreditation Criteria**

ISO/IEC 17025 and ISO 15189 Application Document

Legal - Annex

Policy for the transition of medico-legal drug testing accreditation from AS 4760:2006 to AS/NZS 4760:2019

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**Effective: February 2021** 

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## **Purpose**

This policy is effective from February 2021 and describes changes to the *NATA Accreditation Criteria* (NAC) applicable to all facilities accredited or seeking accreditation both to ISO/IEC 17025 or ISO 15189 and to AS 4760:2006.

### **Background information**

AS 4760:2006 has been superseded by AS/NZS 4760:2019 with both versions of the standard not being comparable.

From August 2021, NATA will no longer offer accreditation for AS 4760:2006 and it is expected that currently accredited facilities update their scope of accreditation to the 2019 version should they wish to remain accredited for AS 4760. The reasons that NATA will no longer offer accreditation for the superseded version of the standard are as follows:

- AS 4760:2006 does not include verification criteria for collection devices:
- cut-off limits for a number of analytes for initial and confirmatory testing have been changed;
- different methodologies are described for laboratory screening;
- additional drugs have been included in the latest version of the standard.

As of 1 August 2021, AS 4760:2006 shall be withdrawn from the scope of accreditation for all facilities.

#### Assessment of facilities to AS/NZS 4760:2019

#### Where a reassessment is due prior to August 2021

Transition from AS 4760:2006 to AS/NZS 4760:2019 will be performed at the next scheduled reassessment where this is due prior to August 2021. The facility's scope of accreditation will be updated once transition is complete.

#### Where a reassessment is not due prior to August 2021

Authorised representatives for facilities not due for a scheduled assessment prior to this date wanting to transition to the latest version of the standard, are to contact their NATA Client Coordinator. In such cases, transition to the latest version of the standard will be performed by desk-top review where no additional activities are to be covered by the scope of accreditation (e.g. Section 2). This will not incur any charges. It is the responsibility of the facility to request transition in a timely manner to allow sufficient time for the desk-top review to occur prior to August 2021.

Where additional parts of the new standard (now able to be accredited) are requested to be added (i.e. Appendix A), an on-site chargeable assessment will be necessary. Refer to the latest *NATA Fee Schedule* available from the website.

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#### **Applicant facilities**

Applicant facilities only have the option to be assessed against AS/NZS 4760:2019 from the issue date of this policy. Where an assessment has already been conducted against the 2006 version of the standard, NATA will liaise with the facility to ensure the requirements of the 2019 version are satisfied prior to granting accreditation to the latest version.

#### **Accredited facilities**

The changes between AS 4760:2006 and AS/NZS 4760:2019 are such that an assessment activity (desk top review or on-site assessment) will be necessary to transition accreditation. This includes the provision of validation data for laboratory testing as described in Sections 4 and/or 5 and verification data as described in AS/NZS 4760:2019 Appendix C2, C3 and C4 for collection devices and onsite screening devices.

Annual NATA membership fees will increase where additional parts of the new standard are requested to be accredited.

#### **Further information**

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

#### References

This section lists publications referenced in this document.

#### **Standards**

AS 4760:2006 Procedures for specimen collection and the detection and

quantitation of drugs in oral fluid

AS/NZS 4760:2019 Procedure for specimen collection and the detection and

quantification of drugs in oral fluid

#### **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
Whole document	Not applicable - new document.

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