# Specific Accreditation Criteria

# Legal ISO/IEC 17025 and ISO 15189 Annex

# Organisations performing on-site medico-legal drug screening in accordance with Australian/New Zealand Standard 4308:2008

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# Organisations performing on-site medico-legal drug screening in accordance with Australian Standard 4308:2008

## 1. Introduction

This Annex describes the various assessment processes adopted by NATA to accommodate the differing operational models of organisations offering on-site drug screening in accordance with AS 4308:2008 *Procedures for specimen collection and the detection and quantitation of drugs in urine, Appendix A On-site screening procedure*.

Organisations may be accredited against ISO/IEC 17025 and/or ISO 15189 as described in the relevant *NATA Accreditation Criteria* (NAC) package for the specific activity types of testing available from the NATA website. Where an organisation operates more than one main site (refer below for definition of a main site) and wishes for these to be covered by a single accreditation, then compliance with *NATA Corporate Accreditations- NATA accreditation of multiple site and/or multiple activity type facilities* must also be satisfied.

## 2. Assessment processes

The various assessment processes are described below and share some common elements.

Initial assessment of the organisation's main site(s) will always occur prior to the granting of accreditation. In some cases, however, the main site performs administrative tasks without screening being undertaken. Should this occur, a single fixed location screening site must be identified as the nominated screening site to be assessed concurrently with the main site.

**Note:** The main site is recognised as the place from where the quality management system is maintained and from where the operations of the organisation are controlled. Peripheral sites may include fixed locations, mobile vehicles or client premises.

Assessment of peripheral sites will include:

2.1 initial assessment of each fixed location (away from the main site) owned by the organisation where accreditation is to be claimed for testing performed at such locations;

2.2 initial assessment of mobile vehicles in which testing is conducted;

**Note:** Each different vehicle set-up type will be assessed. Other factors may also determine the amount of vehicles to be assessed, for example but not limited to, the geographical areas served by the vehicles, the number of vehicles etc.

2.3 initial assessment of activities performed at fixed locations (away from the main site) not owned by the organisation e.g. at client premises;

**Note:** This activity will include a "mock" activity set-up at the organisation's main site and/or an assessment of testing at a client premises.

Once accreditation is granted, the assessment cycle of the main site(s) for the relevant accreditation cycle for ISO/IEC 17025 or ISO 15189 will be in accordance with that described in *NATA procedures for accreditation (After accreditation - surveillance and reassessment)*.

Once accreditation is granted, the assessment cycle of fixed locations, mobile vehicles and/or activities performed at client premises will be as described below. The extent of assessment (assessment effort) will be dependent on each organisation's operational model and may be adjusted when changes to the organisation's accredited services occur.

### 2.1 On-site screening performed at fixed testing location owned by the organisation

Following the granting of accreditation, each fixed location will undergo one on-site reassessment and one surveillance activity per assessment cycle. The latter activity will be coordinated with that of the main site(s). This activity generally will not include a physical visit to the fixed locations, unless deemed necessary, and will include review of records relating to the fixed locations at the main site(s).

### 2.2 On-site screening performed within mobile vehicles

Following the granting of accreditation, the ongoing assessment of vehicles will be tailored for the organisation, taking into account the types of set-up, the number of vehicles for each set-up and the geographical areas served.

Ongoing assessment will include observing testing occurring at a location where a vehicle is stationed.

The organisation must maintain records of the locations where testing has occurred for each vehicle which must be available for review by NATA. The assessment effort of vehicles may be adjusted based on these records.

### 2.3 On-site screening performed at fixed locations not owned by the organisation

Following the granting of accreditation, the ongoing assessment of testing occurring at client owned locations will be tailored for the organisation, taking into account the types of client premises and set-up arrangements.

Ongoing assessment may involve witnessing a 'mock' set up and testing at the organisation's main site and/or witnessing testing at clients' premises.

The organisation must maintain records of the locations where testing has occurred which must be available for review by NATA. The assessment effort of client premises may be adjusted based on these records.

## 3. Scope of Accreditation

NATA must be advised when changes to the activities covered by the Scope of Accreditation occur. This is to ensure that the activities for which accreditation are claimed continue to be covered by the Scope of Accreditation.

### 3.1 On-site screening performed at fixed testing location

The Scope of Accreditation will only be issued to the organisation's main site(s) and identify the fixed testing locations which have been assessed and associated with the main site i.e. the fixed testing locations are not accredited in their own right.

Accreditation can only be claimed for locations identified in the Scope of Accreditation. Prior to claiming accreditation for any new location the organisation must request a variation to the Scope of Accreditation which will involve an assessment of the new location.

### 3.2 On-site screening performed within mobile vehicles

The Scope of Accreditation will only be issued to the organisation's main site(s) which will identify that a mobile testing service is provided.

### 3.3 On-site screening performed at fixed locations not owned by the organisation

The Scope of Accreditation will only be issued to the organisation's main site(s) which will identify that a testing service is provided at client premises.

## 4. Fees

Fees will be in accordance with the current Fee Schedule available from the NATA website.

A cost estimate will be provided at the time of enquiry for seeking accreditation and prior to a request for varying the Scope of Accreditation for existing accreditations.

## 5. Further information

If you have any further queries relating to this Annex, please do not hesitate to contact your Client Coordinator or Andrew Griffin in the Melbourne office on (03) 9274 8200 or by email at Andrew.Griffin@nata.com.au

**AMENDMENTS**

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

| Section | Amendment |
|---|---|
| New document | This document replaces the former Policy Circular 48.<br>The document has been reviewed and updated to reflect the new accreditation criteria documentation structure. |