



Specific Accreditation Criteria

Legal ISO/IEC 17025 and ISO 15189 Annex

Facilities performing on-site medico-legal drug screening in accordance with AS/NZS 4308 and/or AS/NZS 4760

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Purpose

This Annex describes the assessment processes adopted by NATA to accommodate the differing operational models of facilities offering on-site drug screening in accordance with AS/NZS 4308 *Procedures for specimen collection and the detection and quantitation of drugs in urine* and/or AS/NZS 4760 *Procedure for specimen collection and the detection and quantification of drugs in oral fluid*.

Facilities 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 a facility operates from more than one site and wishes for these to be covered by a single accreditation, then compliance with the *NATA General Accreditation Criteria: Accreditation of multi-site facilities* must also be satisfied.

Assessment processes

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

Initial assessment of the facility's main site (see *Note 1*) will always occur prior to the granting of accreditation. Where the main site performs administrative tasks and does not perform onsite screening, a single fixed screening location (see *Note 2*) must be identified as the nominated screening location. This nominated location will be assessed concurrently with the main site.

Note 1: Main site - The fixed physical location, recognised as the place where the management system and technical supervision is maintained.

Note 2: Screening locations - Locations providing screening services under the supervision of the main site are recognised as three types:

- Fixed: permanent location owned and operated by the facility.
- Mobile: Mobile vehicles owned and operated by the facility.
- Premises not owned by the facility: e.g. client premises.

Once accreditation is granted, the assessment cycle of the main site is as per the relevant accreditation cycle of ISO/IEC 17025 or ISO 15189 and in accordance with that described in *NATA Procedures for Accreditation*.

Assessment of screening locations is regarded as an extension of the accredited main site and locations are sampled as part of the assessment of the main site. The [General Accreditation Criteria: Remote assessment policy](#) may be applied. Locations are sampled as follows:

- fixed locations owned by the facility: \sqrt{n} per accreditation cycle, where n = the total number of fixed screening locations owned by the facility;
- mobile vehicles: A minimum of one assessment per vehicle type per accreditation cycle. The facility may be requested to make the mobile vehicle(s) available at the main site or a NATA office;

Note: Records of the number of vehicles, each different vehicle set-up type, geographical area served and details of screening locations and dates must be kept.

- premises not owned by the facility (e.g. clients): A minimum of one assessment is conducted at one client location per accreditation cycle. The assessment includes witnessing a real or 'mock' set up and screening at client premises.

Note: Records of the location of each client screening location visited since the last assessment must be kept.

Change of nominated screening location

The facility must advise NATA in writing as soon as possible. NATA will determine if a chargeable variation assessment is required.

Application to add a new screening location

The facility must advise NATA in writing and provide evidence of:

- screening procedures;
- screening devices;
- statement of the type of screening location;
- evidence to demonstrate main site governance of the new location.

NATA will determine if a chargeable variation assessment is required.

Certificate and scope of accreditation

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

The certificate of accreditation will only be issued to the facility's main site. A certificate is not issued to screening locations as these are not accredited in their own right.

Accreditation can only be claimed for locations identified in the Scope of Accreditation.

Fees

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

A cost estimate may be provided at the time of enquiry for seeking accreditation and when requesting a variation to the Scope of Accreditation for existing accreditations.

Further information

If you have any further queries relating to this Annex, please do not hesitate to contact your Client Coordinator in the first instance.

Amendment table

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

Section	Amendment
All	Reformatted and revised for clarity