This communique is designed to provide laboratories performing in vitro diagnostic medical device (IVD) assays with information about NATA's approach to accreditation and relationship with the Therapeutic Goods Administration (TGA).

NATA's Role in Meeting Regulatory Requirements for In-house IVDs

In-house in vitro diagnostic medical devices (IVDs) are in general, pathology tests that have been developed or modified by a medical laboratory to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management.

Under the Therapeutic Goods Administration's (TGA)[1] new regulatory framework for IVDs that commenced on 1 July 2010, laboratories manufacturing in-house IVDs are required to meet specific regulatory requirements to legally perform their in-house IVDs.

Should a facility supply their IVDs to outside clients they become a commercial IVD manufacturer and will require a different IVD approval process as defined by the regulations.

The National Pathology Accreditation Advisory Council (NPAAC) standard *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices (IVDs)* is one of the key components of the regulatory framework for Class 1-3 in-house IVDs.

This standard sets out the requirements for quality, safety and performance that manufacturers of in-house IVDs must meet to supply their IVDs in Australia.

Compliance and NATA accreditation

Laboratories performing Class 1 -3 IVDs are able to demonstrate compliance with the NPAAC standard and meet TGA regulatory requirements by maintaining NATA/RCPA accreditation under ISO 15189 as a Medical Testing laboratory.

Laboratory organisations with appropriate NATA corporate accreditation can be considered as a laboratory network, and can manufacture and distribute in-house tests within their network.

NATA's role is to assess laboratories for compliance with the NPAAC standards and ISO 15189, and where they are found to meet the requirements, to accredit laboratories which manufacture Class 1-3 in-house IVDs as Medical Testing laboratories.

To ensure the regulatory requirements of in-house IVDs are met NATA will:

- assess compliance with NPAAC standards and ISO 15189;
- review technical documentation for a sample of in-house IVDs (e.g. in-house IVDs implemented or changed since the last assessment);
- conduct an on-site assessment of the laboratory Quality Management System;
- collaborate with the TGA in the accreditation of laboratories and laboratory networks that manufacture in-house IVDs; and
- notify the TGA of any severe compliance issues or deficiencies found in relation to in-house IVD's, where non-conformances are considered not to have been appropriately addressed;

[1] The TGA administers the *Therapeutic Goods Act 1989* and subordinate legislation, such as the Therapeutic Goods (Medical Devices) Regulations 2002, which establish the IVD regulatory framework.

Level 1,
675 Victoria Street
Abbotsford Vic 3067

Freecall: 1800 621 666
Tel: +61 3 9274 8200
Fax: +61 3 9421 0887
Web: www.nata.com.au

ABN 59 004 379 748

National Association of Testing Authorities, Australia is a company limited by guarantee.

Pre-assessment
As part of the pre-assessment process, NATA will request

Applicant laboratories
(also includes accredited facilities proposing assays not previously assessed prior to the last visit :

- the list of in-house IVDs being put forward for accreditation including approximate date of introduction
- a copy of the corporate validation procedure;
- A full validation report for each assay type introduced since 2007;
- Validation **summary** reports for each in-house IVD, including modifications requiring validation, introduced since 2007

For facilities with **all** IVDs assessed at last visit

- the list of in-house IVDs currently in use, including approximate date of introduction
- a copy of the corporate validation procedure;
- A full validation report for each assay type (not each individual test) introduced since the time of the last visit;
- Validation summary reports for each new in-house IVD implemented since the time of last visit
- Validation summary reports for any existing (previously accredited) in-house assays that has undergone changes requiring validation since the time of the last visit.

Assessment
The assessment team will review a sample of in-house IVDs to ensure the availability of appropriate supporting documentation and ongoing monitoring of performance.

The assessment team will also confirm by sampling, the completeness of the list of in-house IVDs notified to the TGA.

There will not be a systematic review of all in-house IVDs previously accredited by NATA, beyond a general review of the laboratory's practices to ensure ongoing compliance with requirements of the standard.

Validation data for assays introduced prior to 2007 which are being assessed for the first time should be made available at assessment. These will be reviewed in conjunction with assay performance data. Facilities will generally not be expect to "re-validate" assays prior to 2007, however, should there be issues identified with the assay in terms of fitness for purpose or poor performance, corrective action will be required.

Should you require any further information please contact Andrew Griffin, Deputy Sector Manager – Life Sciences on (03) 9274 8212 or Andrew.griffin@nata.com.au