# Amendments to the regulatory framework for in vitro diagnostic medical devices (IVDs)

**16 November 2015**

In May 2013, the TGA released a consultation paper, Proposed Amendments to the New Regulatory Framework for In Vitro Diagnostic Medical Devices (IVDs) to address a number of the issues of concern to the IVD sector (both commercial industry and testing laboratories). Subsequently in October 2014, the TGA published a Regulatory Impact Statement recommending further amendments to the framework, particularly in relation to the regulatory requirement for in-house IVDs. These amendments have now taken effect and are summarised below.

**Related information**

- Therapeutic Goods (Medical Devices) Amendment (*In Vitro* Diagnostic Medical Devices) Regulation 2015 - F2015L01791

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## Summary of amendments

### Regulatory requirements for Class 4 in-house IVDs

An alternative conformity assessment procedure has been introduced for laboratories that manufacture Class 4 in-house IVDs. Laboratories can now choose to apply for TGA conformity assessment or use either of the following as evidence of an acceptable Quality Management System (QMS) to support an application for inclusion in the Australian Register of Therapeutic Goods (ARTG):

- TGA issued Good Manufacturing Practice (GMP) licence (satisfying the requirements in the *Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products)*; or
- NATA accreditation as a medical testing laboratory to ISO 15189 and compliance with the NPACC standard, *Requirements for the development and use of in-house IVDs*

When a TGA GMP licence or ISO 15189 are provided as evidence of a QMS, laboratories can apply directly for inclusion of their Class 4 in-house IVD in the Australian Register of Therapeutic Goods (ARTG). The TGA will then evaluate the validation data for the Class 4 in-house IVD (referred to as an application audit). A fee will apply to conduct this application audit.

#### Key dates

- Laboratories with *transitional* Class 4 in-house IVDs will have until 1 July 2017 to apply for inclusion of the IVD in the ARTG.

  Only Class 4 in-house IVDs in use in the laboratory before 1 July 2016 are considered *transitional*.

- Laboratories that choose to rely on their NATA assessment or TGA GMP licence as evidence of a QMS have until 1 July 2017 to submit applications for inclusion of their Class 4 in-house IVDs in the ARTG
- Laboratories that intend to apply for TGA Conformity Assessment Certificates for their Class 4 in-house IVD prior to applying for inclusion in the ARTG need to apply for this certification by 1 July 2016 in order to ensure compliance at 1 July 2017.

- New Class 4 in-house IVDs introduced after 30 June 2016 must be included in the ARTG before they can be used by the laboratory to issue patient results.

## Regulatory requirements for Class 1 - 3 in-house IVDs

The Class 1-3 in-house IVD conformity assessment procedure has been modified to allow the acceptance of NATA accreditation to ISO 17025 as an alternative to ISO 15189 for those laboratories that are considered to be non-medical testing laboratories, (e.g. animal health laboratories). All laboratories are still required to comply with the NPAAC standard, *Requirements for the development and use of in-house IVDs*.

The Class 1-3 in-house notification process has been modified to allow laboratories to broadly identify the types of Class 1-3 in-house IVDs they are manufacturing and will require the attachment of the test list that the laboratory currently provides to NATA for accreditation purposes. Re-notification to the TGA will only be required when the laboratory introduces a new type of in-house IVD which will equate to the introduction of a new in-house test or test procedure to make a new determination or examination as identified on the NATA test list.

### Key dates

Notification of Class 1-3 in-house IVDs must be submitted by 1 July 2017.

## Fees for in-house IVDs

The associated fees for inclusion in the ARTG of a Class 4 in-house IVD and Class 1-3 in-house IVD notification are available in the current Summary of Fees and Charges document.

*Please note: For a class 4 in-house IVD, the fees reflect the maximum payment for an application audit if the full fees were applied. In the majority of circumstances, it is expected that a full assessment would not be required and the fees could be reduced accordingly. For example, if a laboratory has developed a Class 4 in-house IVD by modifying a commercial Class 4 IVD (that has been previously assessed by the TGA), then only the changes made to the commercial product would need to be assessed and the assessment fees could be reduced.*

## Classification of IVDs used to test for transmissible agents included in the Australian National Notifiable Diseases Surveillance System (NNDSS) list

Previously under classification rule 1.3, an IVD intended to detect a pathogen listed on the Australian National Notifiable Disease Surveillance System List (NNDSS) was automatically deemed to be a Class 3 IVD. The reference to the NNDSS in classification rule 1.3 has now been removed resulting in these IVDs being classified in accordance with the remaining classification rules. As a consequence, a small number of IVDs have been down classified to a Class 2 IVD in accordance with rule 1.7.

IVDs intended to detect the presence of, or exposure to, the transmissible agents listed below (that are of public health importance but pose a moderate personal risk because they generally cause self-limiting disease) will be considered Class 2 IVDs:

- Cryptosporidiosis
- Campylobacter
- Hepatitis A virus
- Salmonella enteritidis
- Mumps
- Varicella zoster virus (unless intended by the manufacturer for prenatal screening)
- Barmah Forest virus
- Chikungunya virus
- Ross River virus
- Ornithosis

Screening tests intended to presumptively detect Salmonella at the genus/species level such as individually supplied serotyping reagents that are not intended to identify an individual subspecies/serotype in their own right (e.g., polyvalent and monovalent O antisera) will be considered to be Class 2 IVDs.

Tests to specifically detect/identify Salmonella typhi, including serotyping reagents intended to identify Samonella typhi at the subspecies level (e.g., a serotyping kit intended to discriminate between S. typhi and S. paratyphi), will remain as Class 3 IVDs.

Tests to detect Shiga toxin-producing E. coli or Verotoxin-producing E. coli (STEC or VTEC) including serotyping reagents to specifically identify E.coli 0157:H7 (e.g., 0157 and H7 antisera) will remain as Class 3 IVDs.

### Impact on sponsors with current entries

If, as a result of this change:

- a sponsor has an existing Class 3 entry and all devices under that entry are no longer correctly classified and
- the sponsor does not have an existing Class 2 entry of the same kind

they will be required to submit an application for a new Class 2 IVD entry. For these sponsors, there will be no cost to submit a new Class 2 application. Affected sponsors are advised to contact the TGA through devicereforms@tga.gov.au to discuss how to proceed.

## What happens next

The TGA is in the process of updating guidance materials and these will be released on the TGA website as they become available.

The electronic application form for Class 4 in-house IVDs and the notification form for Class 1-3 in-house IVDs are also being updated. An announcement will be made via the TGA website when these forms are available for use.

## Further information

If you require further information, please contact the TGA by email at devicereforms@tga.gov.au

To ensure you keep up-to-date with further announcements on the IVD reforms, please subscribe to TGA latest news and updates.

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