Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation on proposed changes to IVD medical device classification and definitions

Our response to questions asked during the presentations on 8 May 2025

Version 1.0,

Contents

Introduction

On **8 May 2025**, we hosted a webinar to provide stakeholders with an opportunity to ask questions regarding our public consultation. We received a number of questions both prior to and during the session.

To make it easier to navigate, we have grouped the questions into two main categories:

1. **Transitional Arrangements**
2. **Proposed Changes**

The presentation slides from the webinar are available on the consultation page.

As we were unable to address all questions during the session, we have compiled and summarised the key topics raised. Below, you'll find our responses to the most frequently asked questions.

If you have any further questions, please contact us at IVDs@tga.gov.au

1. Transitional arrangements

1. What happens to the existing registered IVD medical devices that are being reclassified during the transition period and will the TGA allow for continuity of supply for these devices?

   Any changes, including transition arrangements, would be subject to the outcome of the consultation and Government approval. For existing ARTG entries that would be reclassified, we currently propose the following transitional provisions:

   - These devices could continue to be supplied until the transition deadline.
   - Sponsors would be required to liaise with the manufacturer and submit an application for inclusion in the Australian Register of Therapeutic Goods (ARTG) with the amended classification before the transition deadline for that device class.
   - If the ARTG application for the up-classified device is still in progress after the transition deadline, the device may continue to be supplied until the application is finalised.
   - Once a decision is made on the new application, if it is approved, the device will be included in the ARTG. Sponsors must cancel the current ARTG entry if all devices covered under that entry are subject to up-classification.
   - If the new application is refused, supply of the device under the lower-class ARTG entry must cease.

2. Are we required to submit separate applications for the assay and control/instrument if they have different classification from the assay?

   A separate ARTG inclusion application would be required if the assay and the instrument/controls fall under different classifications, as each ARTG entry must be for devices of the same kind.

   Under section s41BE of the *Therapeutic Goods Act 1989*, a device of the same kind refers to a device that shares the same manufacturer, sponsor, classification, GMDN code, and, in the case of Class 4 IVD medical devices and Companion Diagnostics, the same Unique Product Identifier.

3. Will the proposed changes apply to in-house IVDs? What are the implications/requirements to the laboratories existing in house IVDs during the transition period?

   The proposed changes would apply to in-house IVDs, and the transition timelines would also apply.

   Any in-house IVDs that are reclassified from Class 2 to Class 3 would not affect a facility's ability to maintain accreditation. We expect all in-house IVDs to comply with the applicable conformity assessment procedures, which include accreditation requirements under ISO 15189 and National Pathology Accreditation Advisory Council (NPAAC) standards.

   For new in-house IVDs or re-accreditations, the assessment process is risk-based. Accordingly, higher-class in-house IVDs would undergo a more rigorous evaluation. If the changes proceed, you may wish to contact NATA if you have any questions regarding the impact of the proposed changes on the assessment of in-house IVDs.

4. What is the estimated timeframe for the proposed changes be implemented?

   We are unable to provide definitive timeframes for when the proposed changes would be implemented, as this is subject to Government approval. The process involves reviewing the feedback received through this consultation and preparing a proposal for Government consideration. If approved, the regulatory amendments would be drafted, and the approved changes would be implemented when those regulatory changes take effect.

5. If an assay and its dedicated control are of different classifications, does this mean there will be two audits, two fees, two ARTG entries, and two annual charges?

   Currently, the dedicated assay control is included under the same Declaration/ARTG entry as the assay, as it made sense to audit both together given, they cannot function independently.

   If the assay and the control have the same classification, as is the case for control materials with assigned values, and they are supplied together, they can be included under the same ARTG entry. However, if the sponsor intends to supply the controls separately, a separate ARTG entry would be required.

2. Proposed changes

1. What are the key differences between EU IVDR and TGA IVD classification?

   There are a few differences between the EU IVDR and the TGA classification systems. These include, for example, the classification of HIV, HCV, and HBV monitoring IVDs, which are classified as Class D in Europe (equivalent to Class 4 in Australia) but as Class 3 in Australia. Differences also exist in the classification of SARS-CoV-2 and influenza devices, some of which are outlined in the consultation paper.

If you are aware of any other differences, and believe these should not be retained, please provide your feedback as part of the consultation.

2. Will an audit be required on any IVD medical devices that will be up classified from Class 2 to Class 3?

   If your IVD medical device is reclassified from Class 2 to Class 3, you will be required to lodge an application for inclusion in the ARTG. Whether a TGA audit is required will depend on several factors, such as whether the device has been previously audited by the TGA, the type of conformity assessment evidence available (i.e., whether they have conformity assessment evidence issued by the TGA or comparable overseas regulators), and the documentation supporting the ARTG application.

3. Please clarify how the changes may impact (a) controls with assays and (b) assays with instruments.

   Under the proposal, some control materials with assigned values provided by manufacturers, whether qualitative or quantitative, would be reclassified as Class 3 or Class 4 IVDs, depending on the classification of the assays they are intended to verify. Instruments that use reagents with critical characteristics (i.e. assays) would generally remain classified as Class 1 IVDs. Examples are provided in the public consultation paper.

4. Some of the definitional changes appear likely to impact more broadly than IVDs - is this intended?

   The intention of the proposed definitions is to improve clarity. If you believe they may have a broader impact, please provide your feedback to the consultation along with supporting reasons, so this can be considered as part of the proposal.

5. Does the TGA have a list of GMDN codes for the IVDs that will be impacted?

   The TGA does not recommend correlating GMDN codes with the impacted devices. This is due to the use of collective terms that are broad and encompass a large number of devices; not all of which may be affected by the proposal.

   We ask sponsors to review their devices considering the proposed new classification rules and determine whether their device would be up classified. If there are any questions, we encourage them to contact ivds@health.gov.au

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices In Vitro Diagnostics Section	May 2025

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