



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Regulatory requirements for in-house IVDs

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**TGA** Health Safety  
Regulation



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# Contents

<b>Introduction</b>	<b>4</b>
<b>Transitional period for in-house IVDs</b>	<b>4</b>
Class 1-3 in-house IVDs	4
Class 4 in-house IVDs	4
<b>What is an in-house IVD?</b>	<b>5</b>
In-house IVDs developed from first principles	5
IVDs developed or modified from a published source	6
Modifications to commercially supplied IVDs	6
Examples	7
<b>Laboratory networks</b>	<b>7</b>
<b>Conformity assessment procedures for in-house IVDs</b>	<b>8</b>
Class 1-3 in-house IVDs	8
How to comply	8
Post-market requirements	9
Notification of Class 1-3 in-house IVDs	10
Class 4 in-house IVDs	12
TGA conformity assessment	12
Using existing NATA accreditation to ISO 15189 or TGA Manufacturing licence	13
Fees for Class 4 In-house IVDs	14
<b>Post market responsibilities</b>	<b>14</b>
Adverse events	15
Typical causes of adverse events	15
Reporting adverse events	15
<b>Exemptions for in-house IVDs</b>	<b>16</b>
Exemptions for experimental purposes	16
Exemptions to deal with emergencies	16
<b>Relevant legislation</b>	<b>17</b>

## Introduction

Australian laboratories that manufacture in-house in vitro diagnostic medical devices (IVDs) are required to meet regulatory requirements (that commenced on 1 July 2010) to legally supply\* their IVDs in Australia.

The IVD regulatory framework has the following features:

- IVDs must comply with a set of essential principles for the quality, safety and performance of the IVD.
- A risk-based classification scheme requiring different levels of regulation for each class of device.
- There are a choice of procedures (known as conformity assessment procedures), based on the risk classification, to be applied by manufacturers to demonstrate initial and on-going compliance with the essential principles.
- Compliance with recognised standards is used as a means to demonstrate that the essential principles and conformity assessment procedures have been met.
- It includes provisions for post market activities, including monitoring and adverse event reporting.

Laboratories, the Therapeutic Goods Administration (TGA) and the National Association of Testing Authorities (NATA) are involved in ensuring the regulatory requirements of in-house IVDs are met.

This guidance explains how laboratories that manufacture in-house IVDs can meet these requirements.

*\* Supply means making the test available to clinicians and reporting results of the test.*

## Transitional period for in-house IVDs

To allow time for laboratories or laboratory networks to comply with the IVD regulatory framework, the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the MD Regulations) include a transition period for compliance.

### Class 1-3 in-house IVDs

The transition period has been extended to 30 June 2017. Laboratories must comply with the regulatory requirements (and notify us of their Class 1-3 in-house IVDs) by 1 July 2017.

### Class 4 in-house IVDs

The transition period has been extended to 30 June 2017 **but only for Class 4 in-house IVDs in existence before 1 July 2016** (i.e., those Class 4 in-house IVDs in use before 1 July 2016).

Laboratories with transitioning Class 4 in-house IVDs **must** apply for inclusion in the [Australian Register of Therapeutic Goods](#) (ARTG) by 1 July 2017.

If a laboratory chooses to obtain TGA conformity assessment certificates for transitioning Class 4 in-house IVDs prior to applying for inclusion, then **an application for conformity assessment must be submitted to us by 1 July 2016**.

**Class 4 in-house IVDs introduced after 30 June 2016**

These are **not** covered by the transitional arrangements, and **must be included in the ARTG** before they can be used to determine patient results.

## What is an in-house IVD?

'In-house' IVDs are pathology tests that have been developed (or modified) **within a laboratory (or laboratory network)** to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or be used in making decisions concerning clinical management.



IVDs developed in-house but **supplied\* outside** of the laboratory or laboratory network, **fall outside the definition of 'in-house'**.

These are considered to be commercially supplied IVDs, and must be included in the ARTG prior to being supplied outside of the laboratory or laboratory network.

*\* Supply in this context means supply of the actual device, not the testing service, outside the laboratory or laboratory network.*

The regulations are not limited to medical testing laboratories, but extend to all laboratories that manufacture in-house IVDs in Australia.



All diagnostic tests manufactured by a laboratory, regardless of whether or not they attract a Medicare rebate, are still subject to the requirements of the in-house IVD regulatory framework.

In-house tests that are developed by a laboratory for research purposes only (i.e., where there is no reporting of patient results) are not IVDs.

In-house IVDs are defined in Regulation 1.3 of the [MD Regulations](#), and there are three broad situations where a laboratory is considered to have manufactured an in-house IVD.

## In-house IVDs developed from first principles

An in-house IVD is considered to be developed from first principles (*de novo*) where a laboratory or laboratory network is responsible for the design and production of the in-house IVD, and includes:

- design control through assignment of the specifications for the in-house IVD, as well as planning and development processes
- assembly, processing and packaging of components that make up the in-house IVD
- assigning the intended purpose through the information supplied with the in-house IVD (i.e. the instructions for use or laboratory-controlled documents)

- supplying\* the in-house IVD under the laboratory's name (e.g., *ABC Pathology* Influenza A nucleic acid test).

\*Supply means making the test available to clinicians and reporting results of the test.

## IVDs developed or modified from a published source

These include in-house IVDs that are produced by a laboratory or laboratory network:

- in accordance with scientific literature, or
- from the design specifications of an in-house IVD manufactured by another laboratory, or
- from the design specifications of any other source.

They also include the assembly of commercially supplied components, some or all of which may not be regarded as IVDs because they are:

- not finished products, or
- not presented for use as an IVD in the information provided with the device (i.e., manufacturer's labels and instructions for use) and in the advertising, or
- marked "for research use only" (RUO), "investigational use only" (IUO) or "analyte specific reagent" (ASR).

The laboratory is responsible for one or more of the following:

- assembly, processing and packaging of components purchased separately to produce the in-house IVD
- assigning the intended purpose through the information supplied with the in-house IVD (e.g. the instructions for use, laboratory-controlled procedures)
- supplying the in-house IVD under the laboratory's name (e.g. *ABC Pathology* Legionella total antibody assay).

\*Supply means making the test available to clinicians and reporting results of the test.

## Modifications to commercially supplied IVDs

Commercially supplied IVDs become in-house IVDs when:

- they are used for a clinical purpose other than that assigned by the manufacturer
- a physical component of the commercial IVD is modified, substituted or removed
- the IVD is not used in accordance with the manufacturer's instructions for use (i.e., modifications to the instructions for use that could affect the performance of the device and require validation).

The laboratory must document any changes made to a commercially supplied IVD, and be able to demonstrate that the changes have been appropriately verified or when necessary, validated to ensure that the assay performs safely and effectively.

Requirements for the validation and verification of Class 1–3 in-house IVDs are specified in the National Pathology Accreditation Advisory Council (NPAAC) standard, [Requirements for the development and use of in-house in vitro diagnostic medical devices](#).

## Examples

### Modifications that then create an in-house IVD

These include:

- dilution of a component reagent to a concentration other than that specified by the manufacturer.
- substitution of one or more components supplied in a kit, or that are intended by the manufacturer to be used as part of the assay, with an alternatively sourced or laboratory-prepared component.
- substitution of the manufacturer's specified controls with alternative control material.
- modification of the cut-off value, or the calculation specified by the manufacturer for determining the cut-off value, for an assay.
- use of a commercial IVD with a specimen type not specified in the manufacturer's instructions for use.
- use of a monitoring assay to provide a diagnostic result.

### Modifications that are NOT likely to create an in-house IVD

These include:

- utilising variations, alternatives or optional steps included by the manufacturer in the instructions for use or other information provided with the device.
- use of alternative controls where the manufacturer has specified in the instructions for use or other information provided with the device that these can be used.
- use of an alternative reference range that is relevant to the test population, established using a documented process.

These types of modifications would not result in an in-house IVD for regulatory purposes, but you should ensure that any modifications are appropriately verified in accordance with the laboratory's quality management system and accreditation requirements.



If a laboratory imports a commercially supplied IVD directly from an overseas supplier, even when intending to modify that IVD so it becomes an in-house IVD, then the laboratory is the sponsor.

Before importing the IVD, the laboratory must apply for inclusion of the commercial IVD in the ARTG. See the guideline [Including IVD medical devices in the ARTG](#) on our website.

## Laboratory networks

Laboratory networks are a group of laboratory organisations that operate under a single quality management system (QMS). A laboratory network is defined in Regulation 1.3 of the [MD Regulations](#).

The QMS must be managed centrally, and applied uniformly across all work locations which manufacture and use the in-house IVD. However, some local work instructions may be necessary due to location-specific requirements.

As a minimum requirement, the following elements of the QMS must be managed centrally:

- management review
- internal quality audits
- corrective and preventive action
- complaints
- changes to the quality system documentation for key elements.

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

## Conformity assessment procedures for in-house IVDs

Conformity assessment ensures that the manufacturing processes used to make an in-house IVD (and the in-house IVD itself) comply with the regulatory requirements for quality safety and performance.

The class of an IVD determines the conformity assessment procedures a manufacturer can apply to ensure that the device is appropriately assessed, with higher class devices requiring more stringent conformity assessment procedures than lower class devices.

For in-house IVDs, there are different conformity assessment procedures (requirements) for:

- [Class 1-3 in-house IVDs](#)
- [Class 4 in-house IVDs](#).



The **first step** in determining the relevant regulatory requirements is to identify all of your in-house IVDs, and determine whether they are Class 1-3 or Class 4 by referring to the guidance: [Classification of IVD medical devices](#).

### Class 1-3 in-house IVDs

These do not need to be included in the Australian Register of Therapeutic Goods (ARTG). However, laboratories that manufacture Class 1-3 in-house IVDs must comply with the conformity assessment procedure in Part 6A, Schedule 3, of the [MD Regulations](#).

### How to comply

To meet the requirements of this procedure, the laboratory (manufacturer) must fulfil the following criteria.



## Accreditation requirements

- Be accredited by the [National Association of Testing Authorities](#) (NATA), as:
  - a medical testing laboratory to ISO 15189 *Medical laboratories - Particular requirements for quality and competence*<sup>1</sup>, or
  - a non-medical testing laboratory to ISO 17025 - *General requirements for the competence of testing and calibration laboratories*<sup>2</sup>
- Meet the NPAAC standard: [Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices](#)

## Notification requirements

- Submit a notification of all Class 1-3 in-house IVDs being manufactured by the laboratory **by 1 July 2017** (electronic notification to be submitted via TGA Business Services (TBS)).
- From 1 July 2017, notify us of any new Class 1-3 in-house IVDs manufactured by 1 July of the next financial year.



### Note

Laboratories that start manufacturing Class 1-3 in-house IVDs **for the first time after 1 July 2017** must provide their first notification by 1 July of the next financial year.

## Post-market requirements

Implement a post-market system for the ongoing monitoring of the performance of the in-house IVD (e.g., via quality assurance programs and internal quality control) and to notify us of any adverse events (see [Post market responsibilities](#)).

## The role of NATA in Class 1–3 in-house IVD conformity assessment

NATA will assess the laboratory's quality management system against:

- ISO 15189 (for a medical testing laboratory), or
- ISO 17025 (for a non-medical testing laboratory).

The medical testing laboratory accreditation program is administered by NATA in conjunction with the Royal College of Pathologists of Australasia (RCPA). NATA/RCPA accreditation to ISO 15189 is available to laboratories performing tests in various fields of human pathology including anatomical pathology (histology and cytology), chemical pathology, microbiology, haematology, immunohaematology, cytogenetics, molecular biology, immunology and assisted reproductive technologies.

Information about the medical testing laboratory accreditation program is on the [NATA website](#) (see Medical Testing).

<sup>1</sup> Australian standard AS ISO 15189-2013 is identical to, and has been reproduced from, ISO 15189-2012.

<sup>2</sup> Australian standard AS ISO 17025-2005 is identical to, and has been reproduced from, ISO/IEC 17025-2005.

## Review of technical documentation

- NATA inspectors will review the technical documentation for a sample of in-house IVDs (e.g., those that are changed or newly introduced since the time of last inspection).
- The technical documentation will be reviewed for compliance with the NPAAC standard, [Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices](#).

Compliance with this standard will be taken as compliance with the relevant essential principles for the safety and performance of an IVD medical device.

- The level of rigor for the review of selected Class 1-3 in-house IVDs will be commensurate with their risk class (i.e., higher risk Class 3 in-house IVDs will be subject to greater scrutiny than lower risk Class 1 in-house IVDs).
- NATA may notify us of any compliance issue that has or may lead to the death or serious deterioration in the state of health of a patient, user of the IVD, or another person.



Technical documentation will be reviewed by NATA inspectors as part of laboratory accreditation, but the MD Regulations also allow us to request this documentation at any time (if required).

## Notification of Class 1-3 in-house IVDs

### When to provide the initial notification

Laboratories are required to notify us of the Class 1-3 in-house IVDs manufactured **by 1 July 2017** (or within 20 working days of this date).

You can notify us at any time prior to this date, but if new in-house IVDs are introduced in the intervening period (prior to 1 July 2017), you will need to re-notify us to cover the new in-house IVDs before this date.

### Labs who first begin manufacturing in-house IVDs after 30 June 2017

In this case, you must provide your initial notification before 1 July of the next financial year (or within 20 working days of this date).

### Requirements for re-notification post 1 July 2017

Post 1 July 2017, re-notification will be required by 1 July of the following financial year (or within 20 working days of this date) for any new in-house IVDs that have been introduced by the laboratory.

In practice this means that the introduction of an in-house test or test procedure used by a laboratory for a new determination or examination that is required to be added to the laboratory's NATA test list also requires notification to us (by 1 July of the next financial year).

### Examples of when re-notification is not required

- Change to an existing in-house test or test procedure that has previously been notified to us and does not require addition to the laboratory's existing NATA test list.
- Manufacture of an existing in-house IVD has ceased. It is expected that this information would be updated in the next notification for the introduction of any new in-house IVDs.

## Submitting your notification

To submit a notification, the laboratory or an authorised person acting on behalf of the laboratory, must be a TGA 'client'.

Information on how to become a client, and gain access to TGA Business Services (TBS), is available at [TGA Business services: getting started with the TGA](#).

## How to identify your Class 1-3 in-house IVDs in a single notification

You can group similar Class 1-3 in-house IVDs together through the selection of predetermined categories that will be available in the electronic notification form.

### *Information to be attached to your notification*

To further identify the Class 1-3 in-house IVDs you must attach a copy of your NATA test list (also provided to NATA for accreditation purposes). This should identify the individual tests, or test procedures, that are in-house IVDs.

Examples of in-house tests and procedures which could be found on a NATA test list include:

- multiple in-house IVDs that form part of or are used for the same test procedure (e.g., identified on the NATA test list as in-house culture media, in-house stains for general histology)
- a single in-house test to detect a specific marker, analyte or pathogen (e.g., an in-house IVD to detect meningococcal disease)
- a single in-house test to detect multiple specific markers, analytes or pathogens (e.g., a multiplex PCR for respiratory pathogens)
- an in-house test procedure that incorporates a combination of individual markers, analytes or pathogens using the same testing platform or technology, and which are interpreted together in order to determine a specific condition (e.g., an in-house test to determine haematological malignancy using a panel of CD markers used in flow cytometry)



If you are unable to identify an appropriate category in the electronic notification form for your in-house IVD, please contact us for assistance at: [devices@tga.gov.au](mailto:devices@tga.gov.au)

## Notification fees

Current notification fees are available in the [TGA summary of Fees & Charges](#).

- A notification fee applies to the initial notification, and to any subsequent re-notifications, and only one fee is charged per notification.



All Class 1–3 in-house IVDs manufactured by a laboratory (or a laboratory network) can be entered in the in-house IVD database in a single notification.

## What happens once the notification is submitted

- Once submitted (and the notification fee processed), the laboratory's details will be entered in the in-house IVD notification database.
- We will then send the laboratory an email advising them of the notification, and they will be able to view\* their notification via their TBS account.

*\*The in-house IVD notification database is not publically viewable.*

## Class 4 in-house IVDs

Laboratories that manufacture Class 4 in-house IVDs must:

- include them in the ARTG
- comply with the conformity assessment procedures in Part 1 or Part 6B, Schedule 3, of the MD Regulations.

To do this, laboratories have a choice of two (2) pathways:

1. Obtaining [TGA conformity assessment](#) certificates prior to applying for inclusion of their Class 4 in-house IVDs in the ARTG;
- or**
2. Using their [existing NATA accreditation to ISO 15189, or their TGA Manufacturing licence](#), to apply directly for inclusion of their Class 4 in-house IVD in the ARTG.

## TGA conformity assessment

Manufacturers of commercially supplied Class 4 IVDs are required to undergo TGA conformity assessment, and the manufacturer must apply for (and obtain) a TGA conformity assessment certificate **before** they can apply for ARTG inclusion.

This pathway is also applicable to the manufacturers of Class 4 in-house IVDs that:

- don't currently hold valid NATA accreditation or a TGA issued licence to manufacture therapeutic goods, and
- don't intend to obtain either of these in the future.

For this procedure, the laboratory will need to apply to us for a:

- quality management system (QMS) certificate for the laboratory
- design examination (DE) certificate for each Class 4 in-house IVD.

## Assessment process

- We will conduct an assessment for compliance with ISO 13485:2003 *Medical devices - Quality management systems - Requirements for regulatory purposes*. This details the requirements for a quality management system for the design and manufacture of medical devices.

**Note:** This process may also involve an on-site inspection.

- As part of conformity assessment, we will also assess the technical documentation (i.e., analytical and clinical performance data) for the Class 4 in-house IVD to assess compliance with the essential principles for safety and performance.

- If successful, we will issue the laboratory with a TGA Conformity Assessment QMS certificate and a DE Certificate for the Class 4 in-house IVD.

Once issued, the laboratory can then apply for inclusion of the Class 4 in-house IVD in the ARTG.



Applications for a TGA conformity assessment certificate for transitioning Class 4 in-house IVDs must be submitted to us by 1 July 2016.

Laboratories are encouraged to contact us on 1800 141 144 to arrange a pre-assessment meeting with the IVD Conformity Assessment team prior to submitting the conformity assessment certificate application.

## Further information

For further information on TGA conformity assessment, see:

- [Conformity assessment overview \(IVDs\)](#)
- [What a manufacturer needs to know about conformity assessment \(IVDs\)](#)

## Using existing NATA accreditation to ISO 15189 or TGA Manufacturing licence

In this pathway, a laboratory can apply directly to include their Class 4 in-house IVD in the ARTG (i.e. without needing a TGA conformity assessment certificate) if they either:

- Are accredited by NATA to ISO 15189 as a medical testing laboratory; **and** comply with the NPAAC standard, [Requirements for the development and use of in-house IVDs](#).

**or**

- Hold a current TGA issued Manufacturing licence that authorizes the carrying out of a step in the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods; **and** the laboratory satisfies the requirements in the [Australian Code of Good Manufacturing Practice for Blood and Blood Components, Human Tissues and Human Cellular Therapy Products](#).

## Mandatory application audit

The application will be subject to a mandatory application audit, where we will assess the analytical and clinical evidence for the Class 4 in-house IVD to determine compliance with the relevant Essential Principles prior to ARTG inclusion.

For a Class 4 in-house IVD based on the modification of a commercially supplied Class 4 IVD already included in the ARTG, only the changes made to the commercially supplied IVD will be assessed.

Laboratories may also be required to provide evidence that they have appropriate procedures in place that allow them to monitor the on-going performance of the device and report any adverse events or problems associated with its use (see [Post market responsibilities](#)).

## Further information

For more information on including Class 4 in-house IVDs in the ARTG, please see:

- [What a sponsor needs to know about conformity assessment \(IVDs\)](#)
- [Including IVD medical devices in the ARTG](#)

## Fees for Class 4 In-house IVDs

Current fees are available in the [TGA summary of Fees & Charges](#), and the total fees payable will vary depending on the chosen pathway.



The assessment fees reflect the maximum payment **if the full fees were applied**. In the majority of circumstances, a full assessment would not be required, and the fees could be reduced.

For example, if a laboratory has developed a Class 4 in-house IVD by modifying a commercially supplied Class 4 IVD (that has been previously assessed by us), then only the changes made to the commercially supplied product would need to be assessed and the assessment fees could be reduced.

## TGA conformity assessment

If a laboratory chooses to obtain TGA conformity assessment certificates prior to applying for inclusion in the ARTG, then the following fees will apply:

- Application fee for TGA conformity assessment certificate
- A full quality management system inspection fee\* (fee for evaluation of the QMS)
  - \*Additional fees may apply if an on-site inspection is required.
- A design examination fee for each Class 4 in-house IVD (fee for evaluation of the technical documentation)
- Application fee for inclusion in the ARTG

## Using existing NATA accreditation to ISO 15189 or TGA manufacturing licence

If a laboratory chooses to apply directly for inclusion in the ARTG based on already having NATA accreditation to ISO 15189 or a TGA issued Manufacturing licence, then the following fees will apply:

- Application fee for inclusion in the ARTG
- Application audit assessment fee for Class 4 in-house IVDs (fee for evaluation of the technical documentation)

## Post market responsibilities

The MD Regulations require laboratories that manufacture in-house IVDs to have a QMS in place that allows them to:

- monitor the performance of their IVDs by systematically reviewing the application of quality control (QC) procedures and participation in external quality assurance (EQA) programs
- apply necessary corrective action if any failures (or potential failures) are detected in relation to the performance of the in-house IVD
- report any adverse events relating to the safety, quality or performance of their in-house IVDs to us

- notify us\* of any malfunction or deterioration in a Class 4 in-house IVD that has led the laboratory to take steps to cease using or recover the device if it has been disseminated within a laboratory network.

\*Send this notification to the TGA Recalls Unit in accordance with the requirements of the [Uniform Recall Procedure for Therapeutic Goods \(URPTG\)](#).

The [NPAAC standard](#) (Sections 9 and 10 - *Particular requirements – monitoring, analysis and improvement* and *Particular requirements – adverse event reporting and recalls*) provides guidance on the necessary monitoring and post market activities for in-house IVD manufacturers.

## Adverse events

An adverse event includes an event that leads to:

- the death of a patient
- a serious injury or serious deterioration to a patient, user or other person, including a life-threatening illness or injury
- permanent impairment of a body function
- permanent damage to a body structure
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

## Typical causes of adverse events

- design issues
- deficiencies in instructions
- defective components
- performance failures
- user/systemic errors

## Reporting adverse events

The MD Regulations prescribe that information must be reported to us about events related to the use of medical devices (including in-house IVDs) that represent:

- a serious threat to public health
- the death of a person
- a serious deterioration in the health of a person.

Regulation 5.7 prescribes the timeframes where information about adverse events must be reported to us:

Event (or other occurrence)	Timeframe required for reporting <i>(after the person becomes aware of the event or occurrence)</i>
Represents a serious threat to public health	48 hours
Led to the death, or a serious deterioration in the state of health, of a person* <i>* a patient, a user of the device, or another person</i>	10 days
Where a recurrence might lead to the death or a serious deterioration in the state of health, of a person* <i>* a patient, a user of the device, or another person</i>	30 days

For further information on reporting adverse events for medical devices, see [Report a medical device adverse event \(sponsor/manufacturer\)](#).

## Exemptions for in-house IVDs

Therapeutic goods legislation provides exemptions for IVDs that are used for evaluation or experimental purposes, or to deal with emergencies.

### Exemptions for experimental purposes

Schedule 4 Part 2 of the MD Regulations sets out the provisions for exempting medical devices for experimental purposes.

Laboratories that need access to an unapproved commercially supplied IVD, or need to develop a Class 4 in-house IVD for experimental purposes, should contact us to discuss the requirement for an exemption.

### Exemptions to deal with emergencies

Part 4-6A of the Act allows for certain therapeutic goods be stockpiled to deal with possible future emergencies, or made available urgently to deal with actual emergencies.

For example, Class 4 in-house IVDs that have been developed by laboratories to detect an emerging infectious disease may be exempted from the need to be included on the ARTG in the national interest, to deal with a possible emergency.

Laboratories that manufacture in-house IVDs for these purposes should contact us to discuss the requirement for an exemption.



This type of exemption **can only be initiated by the Government** (i.e., not by an individual laboratory) in the event of an actual public health emergency or potential emergency.



## Relevant legislation

The legislation applicable to in-house IVDs is:

- [\*Therapeutic Goods Act 1989\*](#)
- Part 6A, Schedule 3, of the [\*Therapeutic Goods \(Medical Devices\) Regulations 2002\*](#) (for Class 1-3 in-house IVDs)
- Part 1 or Part 6B, Schedule 3, of the [\*Therapeutic Goods \(Medical Devices\) Regulations 2002\*](#) (for Class 4 in-house IVDs)

## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	IVD Section	January 2012
V2.0	Updated to reflect recent amendments to regulatory requirements.	IVD Section	March 2016

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