# Refresher on Regulatory framework in-house IVDs

Shraddha Swami
Director, Devices In Vitro Diagnostics Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration

# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

# Session outline

1. Definition of IVD and in-house IVD
2. Legislation and Regulatory requirements
3. Role of TGA
4. Common Issues with compliance
5. Work in progress

# Definition of IVD medical device

## Definition of IVD in the Regulations

- A reagent, calibrator, control material, kit, specimen receptacle, instrument, software, equipment or system
- Intended for the in vitro examination of human specimens for:
  - giving information about a physiological or pathological state
  - giving information about a congenital abnormality
  - determining safety and compatibility with a potential recipient
  - monitoring therapeutic measures

### Not a product that is:

- Intended for general laboratory use, and
- Not manufactured, sold or presented for use as an IVD medical device

This definition can be found in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

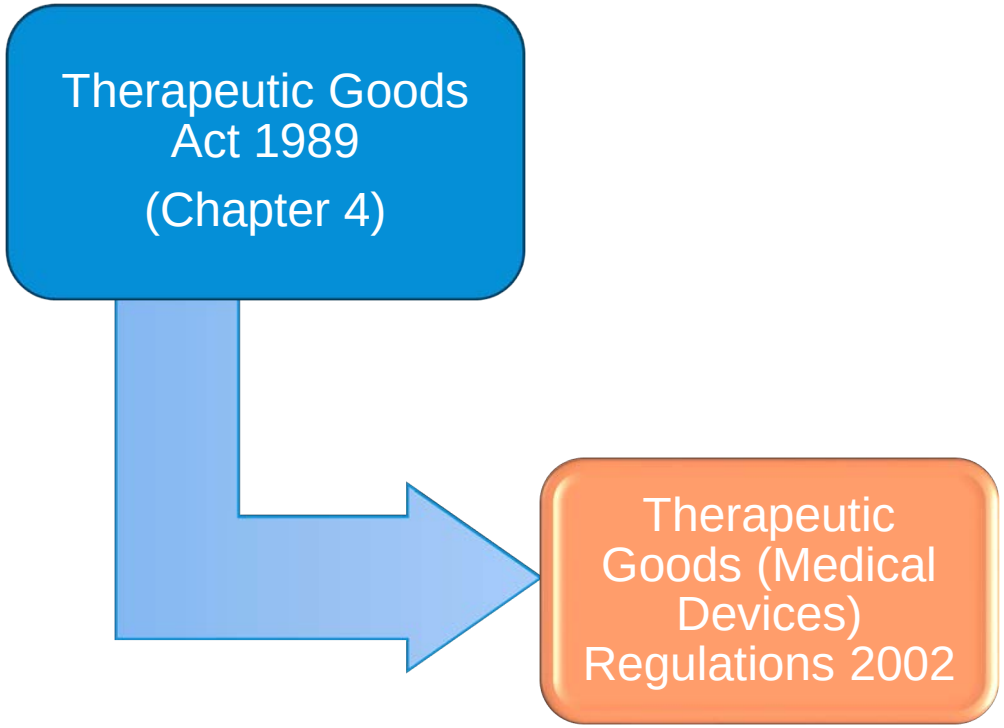
# What is an in-house IVD?

## Manufactured by a laboratory for use in that laboratory or laboratory network

- Developed from first principles
- Developed or modified from a published source
- Developed or modified from any other source (e.g. commercial IVD, RUO products)
- Used for a purpose other than the manufacturer’s intended purpose

# Medical device legislation

All regulatory decisions for IVDs are made using the legislation:




See our Legislation and legislative instruments page on our website for a list of Acts, regulations and legislative instruments.

# Exemption Provisions

All therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG), before they can be legally supplied in Australia, unless exempt. Some exemption provisions:

- Experimental purposes
- Special Access Scheme or Authorised Prescriber Scheme
- Emergency exemption
- Exemption with conditions

# Overview of IVD Regulation

- Prior to 2010, IVDs were regulated in Australia as ‘Other Therapeutic Goods’ (OTGs)
- Regulatory framework for IVDs commenced in July 2010.
- IVDs are regulated as a subset of medical devices, using same risk-based framework.
- IVD framework also includes the in-house IVD medical devices with similar risk-based classification but has differences with regulatory oversight.

# Classification of IVDs

The classification IVDs are determined by the risk posed to the health of an individual or the public.

Applicable to both commercial and in-house IVDs

| Class | Examples | Risk |
|---|---|---|
| **Class 1 IVD** | • Sample collection container<br>• Microbiological culture media | No public health risk or low personal risk |
| **Class 2 IVD** | • Pregnancy and fertility self-testing kits<br>• Cholesterol test | Low public health risk or moderate personal risk |
| **Class 3 IVD** | • Tests to detect a sexually transmitted disease (e.g., chlamydia, gonorrhoea)<br>• Human genetic tests | Moderate public health risk or high personal risk |
| **Class 4 IVD** | • Blood donor screening tests for HIV | High public health risk |

See Classification of IVD medical devices for more information. These classification rules are written within Schedule 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

# What does a laboratory need to do?

**Determine the risk class of IVD based on the intended use**

**Comply with the risk classification-based regulatory requirements:**

Applicable conformity assessment procedures

Level of technical documentation

Regulatory obligations

# Conformity Assessment Procedures

Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device (including IVD medical devices) complies with the Essential Principles.

Related to:

- Use of a Quality Management System for developing IVD medical devices
- Post market monitoring of devices and
- Record keeping and producing, when requested.

# Conformity assessment procedure for Class 1-3 in-house IVDs

Laboratories manufacturing Class 1-3 in-house IVDs must:

- Maintain accreditation by NATA to the requirements of *ISO15189 – Medical Laboratories – Particular requirements for quality and competence*
- Meet requirements of the NPAAC performance standard *Requirements for the development and use of in-house IVDs*
- Notify all in-house tests to the TGA annually for entry onto a database

# Conformity Assessment Procedures – class 4 in-house IVDs

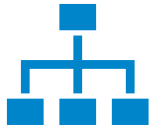
| Conformity Assessment (CA) Procedures | Requirements for Class 4 in-house IVDs |
|---|---|
| TGA CA | Same as for commercial Class 4 IVDs:<br>• TGA CA certification |
| NATA accreditation (ISO 15189) or TGA GMP licence | Apply directly for inclusion in ARTG<br>• Subject to mandatory application audit |

# Technical documentation

All in-house IVDs irrespective of the classification – Need to comply with the Essential Principles.

Essential Principles are safety and performance requirements that apply to your device.

# Post market requirements



Monitor the performance 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 TGA of any malfunction or deterioration of an in-house IVD that has led the laboratory to take steps to cease using the device

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

# Regulatory exemptions for in-house IVDs

## Exempt – but with conditions

- Class 1 to 3 in-house IVD

  Must comply with the Essential Principles and the Conformity assessment procedures – Make information available to TGA, when requested.

- Class 4 in-house IVD

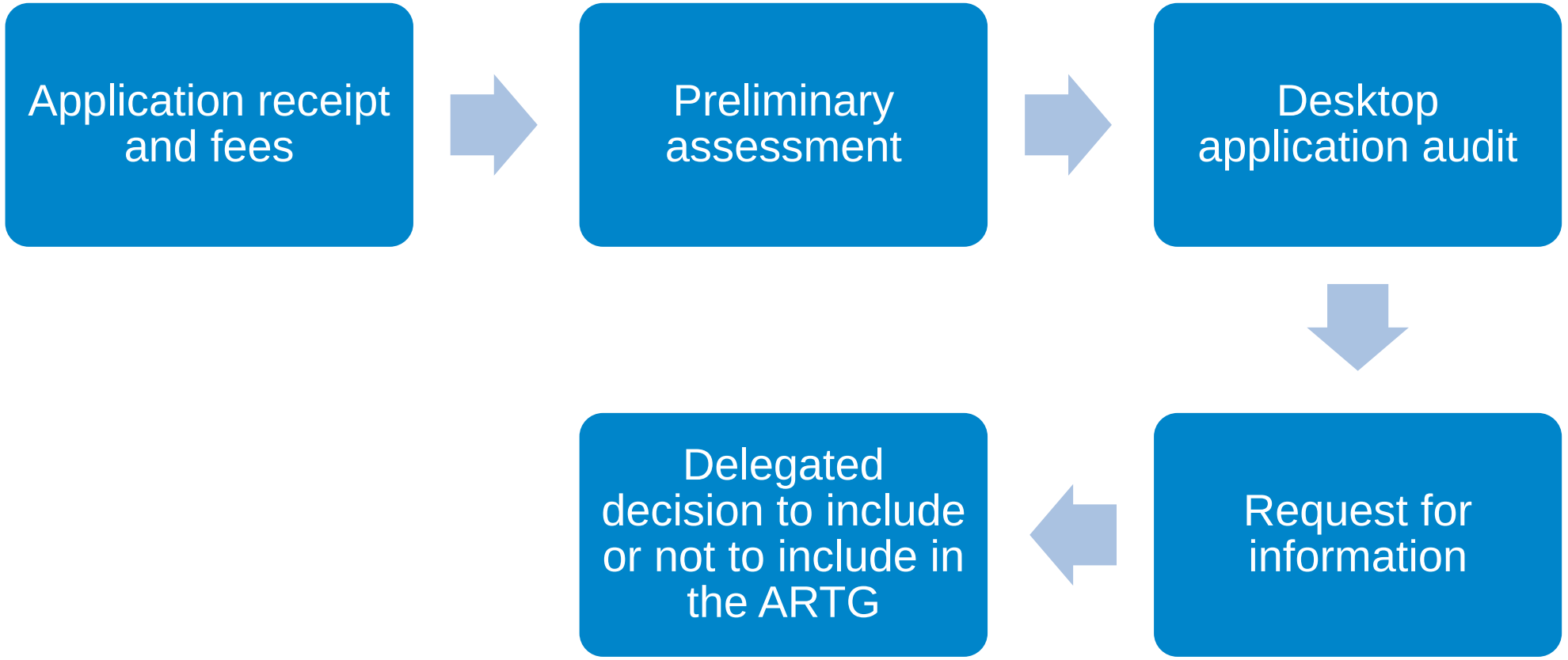
  Screening of donors for use in Faecal Microbiota Transplant manufacture

  – Have data to demonstrate the safety and performance requirements.

  – Notification of device manufactured

# Inclusion in the ARTG

## IVD inclusion process



# Inclusion in the ARTG

## IVD inclusion fees

### Application fee

- Application for inclusion into the ARTG of all classes of IVD, including Class 4 in-house IVDs (excluding export only IVD devices): $1,098

### Application audit assessment fees

- Class 4 in house IVD medical devices: $22,387*

No annual charge for class 4 in-house ARTG entries

See more information on the TGA website: Summary of fees and charges to applications submitted to the TGA

* Proposal currently under consideration to further reduce this fees.

# Overview of in-house IVD Regulation

| | |
|---|---|
| Class 1<br>2<br>3 | NATA accreditation (e.g. ISO 15189)<br>NPAAC Validation Standard<br>ARTG exempt - Annual notification to TGA<br>Post market requirements |
| Class 4 | Same as for commercial IVDs<br>Conformity Assessment under Part 1 or<br>Apply directly for inclusion in the ARTG<br>Comply with ARTG conditions of inclusion |

# Role of TGA

- Maintain database of Class 1-3 in-house IVD notifications

- Issue conformity assessment certificates for Class 4 in-house IVDs & inclusion in ARTG

- Regulatory oversight to ensure in-house IVDs meet compliance requirements and

NOT

Regulation of clinical or laboratory practice

# MoU with NATA

## Sets out roles and responsibilities of NATA & TGA

- Oversight of Class 1-3 in-house IVDs designated to NATA
- Facilitates information sharing between NATA and TGA
- NATA can request TGA to provide officers as technical assessors for participation in laboratory accreditation activities and desktop audits (in relation to Class 1-3 in-house IVDs)
- TGA to inform NATA of adverse events related to in-house IVDs

See more information on the TGA website: TGA-NATA MoU relating to the regulation of in-house IVDs

# Issues with compliance

- Lack of awareness of post market requirements
- Lack of notification of manufacture of class 4 in-house IVD
- Use of Investigational Use Only device for the purposes of supply (i.e., reporting results and using it for clinical and patient management)

# Work in progress

New In-house IVD notification form and updated guidance

Updated CDx guidance document for public consultation

Publication of TGA CDx list – Initially will only include commercial IVDs with the next phase to include in-house CDx.

# Coming up next:

- NATA TGA IVD Information Session 2: Data requirements and assessment approach including Companion Diagnostics

## Questions?

natatgaivd@nata.com.au

OR

ivds@health.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration