Introduction of new In-house IVD notification form

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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.

Introduction of new In-house IVD notification form

Session outline

1. What is an in-house notification form
2. Issues with the existing form
3. Introduction of the updated form and new template
4. Notification Process
5. Transition timelines

What is an in-house notification form

You must notify TGA if you intend to supply a Class 1-3 in-house IVD

Recap

- Classification of the device is based on the intended purpose for the device and classification rules in Schedule 2A of the Therapeutic Goods (Medical Devices) Regulations 2002
- Class 1-3 In-house IVDs require annual notification prior to 1st of July of the financial year.
- A notification is only required, if a new Class 1-3 in-house IVD **has been** introduced since the previous notification.

Issues with the current notification form

- Lack of consistency in data provided between laboratories.
- Data often not provided in a systematic and ordered manner.
- Data storage issues – Data from one form cannot be combined with another
- Lack of search functionality, due to collection of data in an unsuitable format.

Old Form Functionality (example)

IVD details

Does this notification include any IVDs intended for use as a companion diagnostic? ○ Yes ○ No

IVD Type: -- Select --

IVD Category:

Add (Click on the bin icon to remove Type and Category)

IVD details

Does this notification include any IVDs intended for use as a companion diagnostic? ○ Yes ◉ No

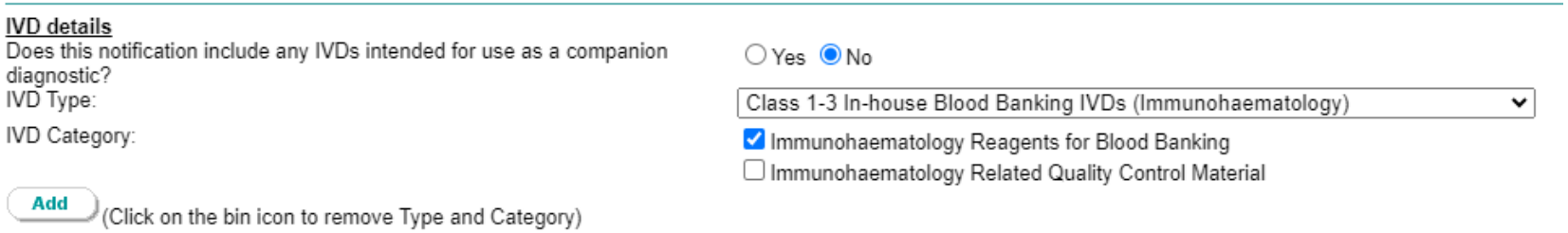
IVD Type: Class 1-3 In-house Histology & Cytology IVDs

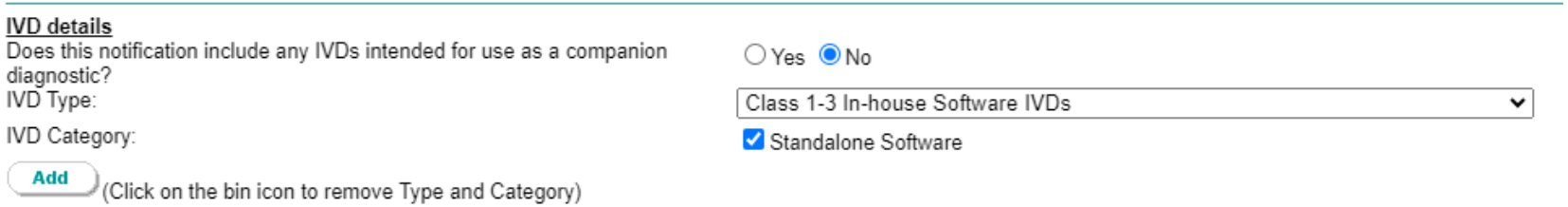
IVD Category:

- ☐ Histological/Cytological Stains
- ☐ Histology & Cytology Related Quality Control Material
- ☑ Immunohistochemistry
- ☐ In Situ Hybridisation
- ☐ Other Histology & Cytology Related Tests

Add (Click on the bin icon to remove Type and Category)

Old Form Functionality (example)





Changes to the existing form

- Minor updates to the existing notification form.
- Introduction of mandatory standardised excel template for data consistency and completeness.
- Allows for storage of information to enable searchability function.
- Consistency by alignment of IVD type and IVD category with NATA categories.

Introduction of new standardised excel template

It will be mandatory to attach the completed standardised excel template with the in-house notification form.

Updated guidance will be published soon with information on the form and the new excel template.

Please note, any notification that is submitted without the standardised templated will not be accepted. The form will be pushed back, and the laboratory will be asked to notify with the correct (completed) template.

Refer to the guidance for the use of the Class 1-3 in-house IVD notification form - Class 1-3 in-house IVDs: using the online application form

The Template

Laboratory Network: *Name and NATA accreditation number of the facility*	**Laboratory Name:**	**Site Identifier:** *NATA site identifier number*		**Use this test list template to notify Class 1-3 in-house IVDs.** **All Class 1-3 in-house IVDs must be notified using this template by 1 July of the year following the introduction of the new device.** **Any new notifications or changes must be added to the current version of your test list before this is re-submitted, so that all in-house IVDs currently in use within your laboratory (or laboratory network) are listed below.** **Do not use this template to notify Class 4 in-house IVDs - you need to make a separate ARTG application for each Class 4 in-house IVD (unless otherwise exempt).**								
e.g. Pathology Queensland Accreditation number 2639	e.g. Central Laboratory	e.g. 2632											
	e.g. Nambour Laboratory	e.g. 5485											
Insert extra rows here if required													
Test name	**Site Identifier**	**Category**	**CDx**	**Notification year**	**Indication/Determination**	**Specimen**	**Instruments**	**Software**	**Commercial test**	**Modification**	**LDT**	**Class**	**Comments**
Name of the test	*List the identifier number(s) for the sites where this test is performed*	*Category of testing performed*	*Is this a Companion Diagnostic test?*	*Please indicate if this is a new device; a change to a device; or a previously notified device (state year of notification)*	*Please provide general information regarding the nature and purpose of the in-house IVD test (or test group).* *For CDx tests, list the indication including disease status and medicine/biological product*	*All specimen types validated for use with the test*	*Instrument(s) to be used with the test, including model number if known*	*Software separately supplied to the instrument(s), including version number if known*	*If applicable, the commercial test from which the in-house test was developed (including manufacturer and device name)*	*For in-house IVDs developed from commercially supplied devices, please provide a description of the modification, e.g. additional sample type, modification to process, new indication, etc*	*If developed from first principles or a Research Use Only (RUO) kit (and not from an existing commercially supplied device), please indicate if the device is a laboratory developed test (LDT) - Y/N*	*Select the class of IVD (i.e. Class 1 - 3 in-house IVD)*	*Add any comments you would like to include*

Template requirements

There are 14 available data fields with selectable fields and filters

- Test name
- Site Identifier
- Category
- Companion Diagnostic
- Notification Year
- Indication/Determination
- Specimen
- Instruments
- Software
- Commercial Test
- Modification
- Laboratory Developed Test
- Classification
- Additional comments

Field descriptions/required information

- Instruments: Instrument to be used with the test, including model number, if known.
- Software: Software separately supplied to the instrument, including version number if known.
- Commercial Test: If applicable, the commercial test from which the in-house test was developed (including manufacturer and device name).
- Modification: For in-house IVDs developed from commercially supplied devices, please provide a description of the modification, e.g. additional sample type, modification to process, new indication, etc.
- Laboratory Developed Test (LDT): If developed from first principles or a Research Use Only (RUO) kit (and not from an existing commercially supplied device), please indicate if the device is LDT - Y/N.
- Class: 'Select the class of IVD (i.e. Class 1 - 3 in-house IVD).
- Comments: Add any comments you would like to include.

The Data tab

The Data Tab is locked and cannot be changed by users. This Tab contains the options for the drop-down menus in the spreadsheet.

Test name	Site Identifier	Category	CDx
Name of the test	*List the identifer number(s) for the sites where this test is performed*	*Category of testing performed*	*Is this a Companion Diagnostic test?*
	e.g. 2632, 5485		

Category
Please select from the list of categories

Class data	Category data	CDx
Class 1 in-house IVD	Anatomical Pathology - Cytopathology	Yes
Class 2 in-house IVD	Anatomical Pathology - Tissue Pathology	No
Class 3 in-house IVD	Chemical Pathology	
	Cytogenetics	
	Haematology	
	Immunohaematology	
	Immunopathology	
	Infertility and Pregnancy Tests including Assisted Reproductive Technology	
	Microbiology - Bateriology	
	Microbiology - Environmental Investigations and/or Infection Control	
	Microbiology - Molecular Biology	
	Microbiology - Mycobacteriology	
	Microbiology - Mycology	
	Microbiology - Parasitology	
	Microbiology - Serology of Infection	
	Microbiology - Virology	
	Molecular Genetics	
	Non-clinical Biomarkers	

The Data tab – continued

- Right click on the Class 1-3 on-house notification Template Tab
- Select the Move or Copy option, select the appropriate Tab from the available Tabs and select ‘Create a copy’.
- A new Tab will be created with the same name as the copied Tab.
- Using the rename function each Tab can be identified with the department name.
- NOTE: all departments can be included in the same Tab. The use of separate Tabs is an available option and not a requirement.

Updates to the existing notification form

Before selection

IVD details

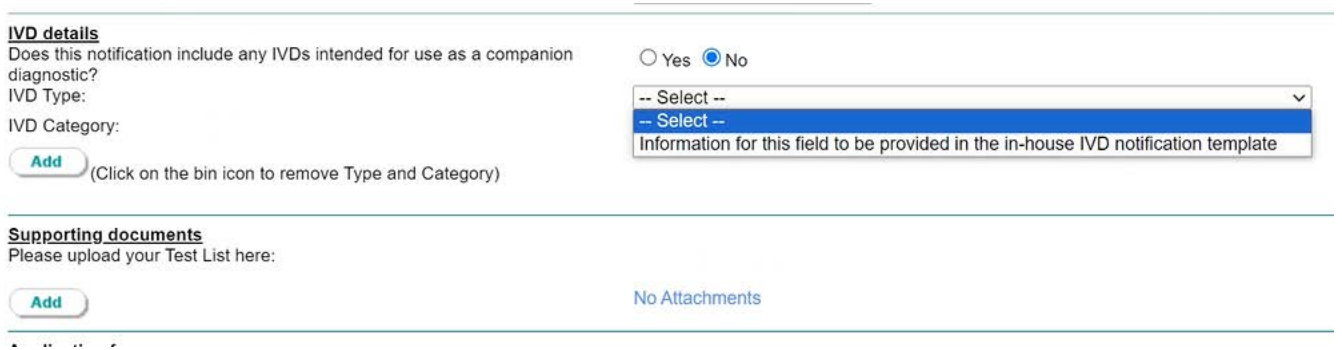
Does this notification include any IVDs intended for use as a companion diagnostic? ○ Yes ○ No

IVD Type: -- Select --

IVD Category:

Add (Click on the bin icon to remove Type and Category)

After selection

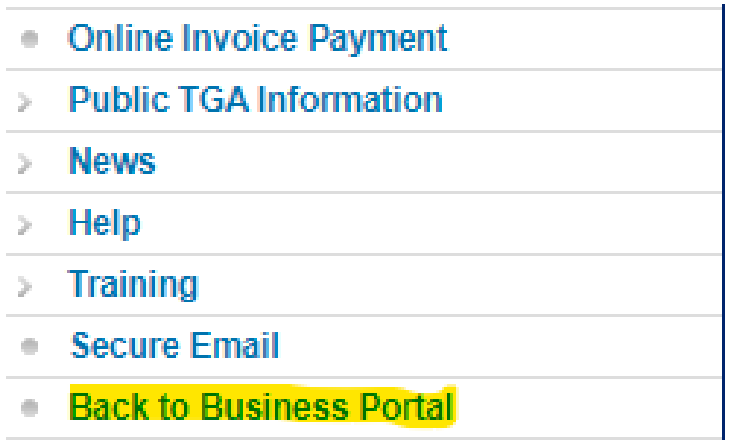


How to complete the form – new in-house IVD manufacturers

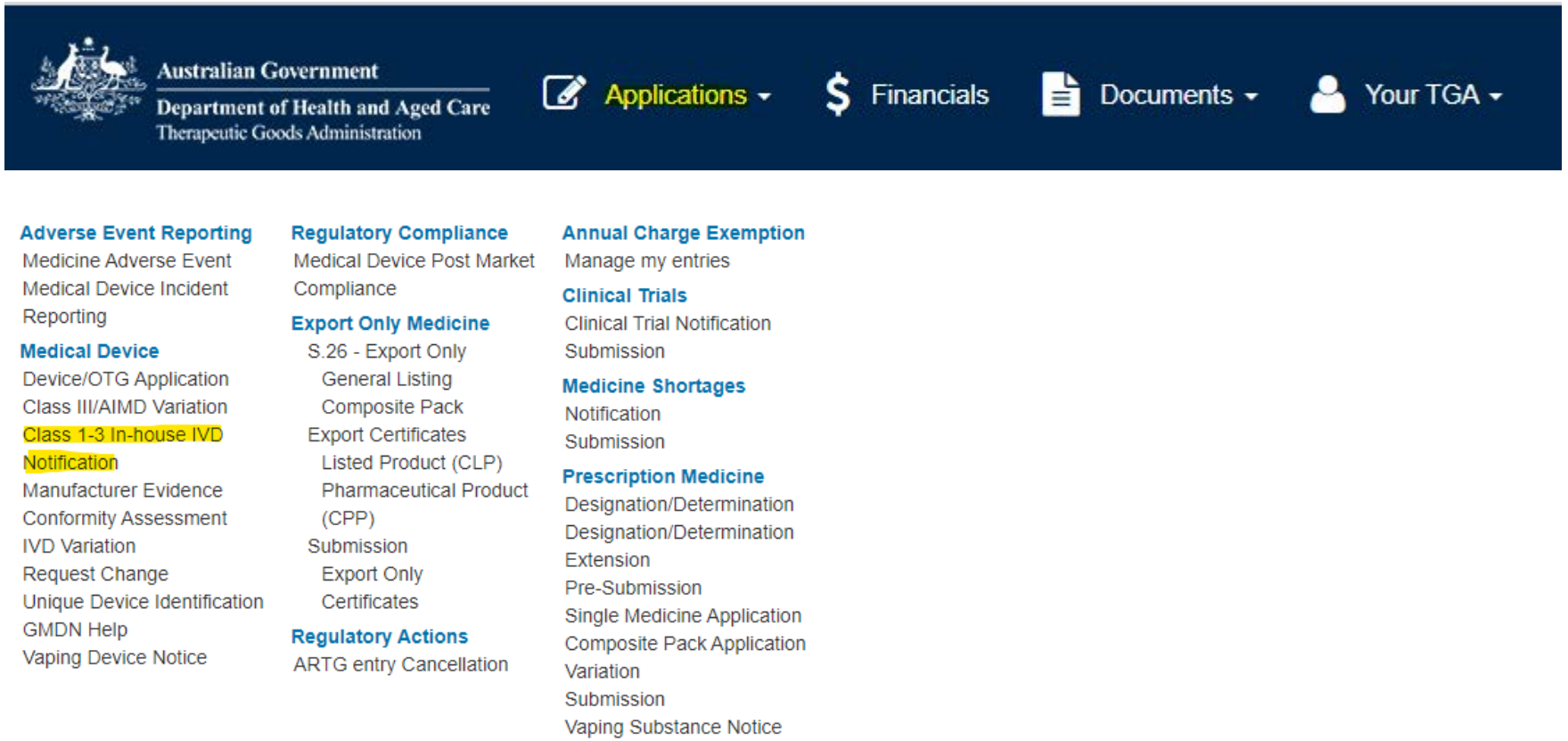
The TGA Business Services Portal (TBS) allows the manufacturer (laboratory) to submit notifications to the TGA

Preparing for notification

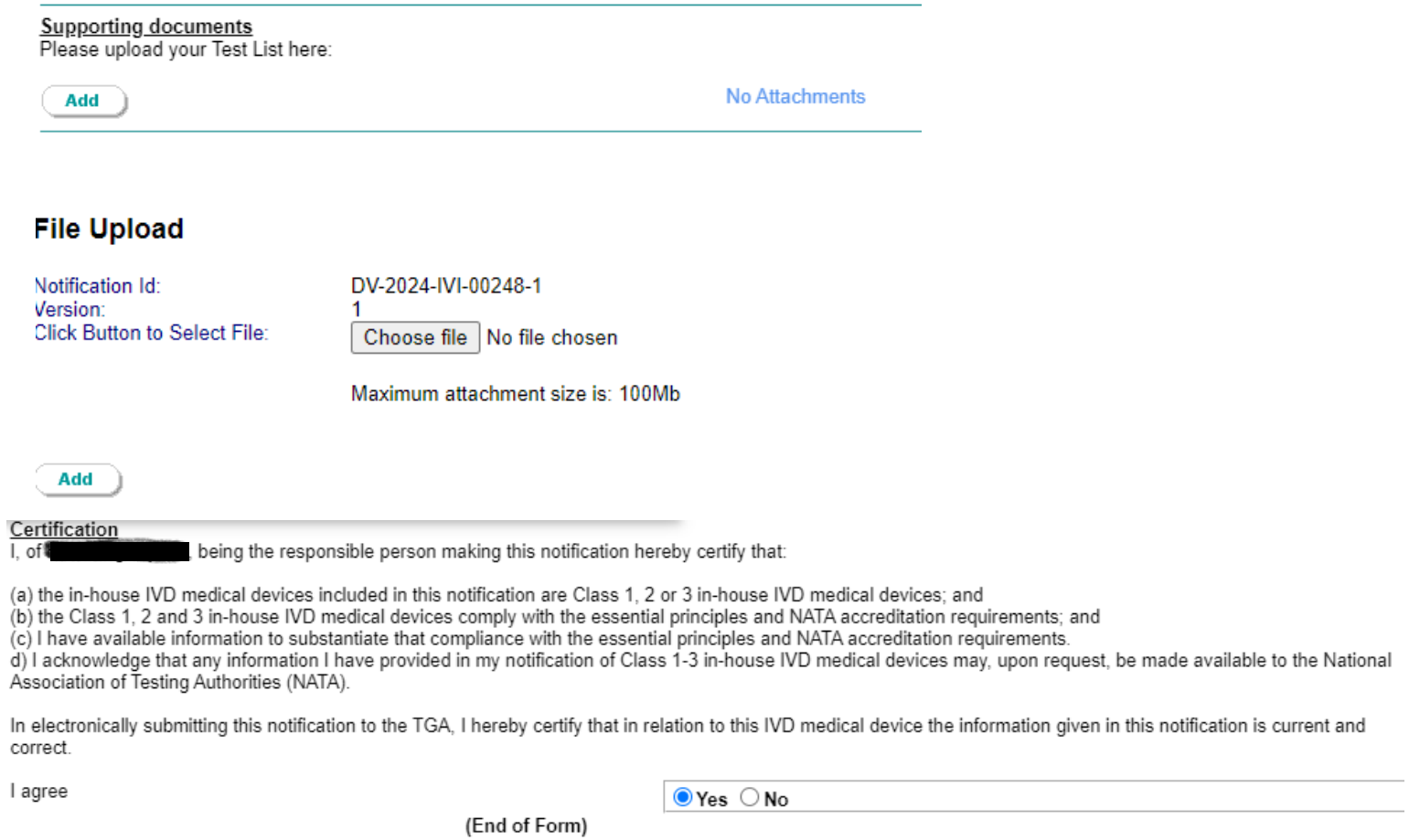
Requires access to TGA Business Services Portal (use of Google Chrome recommended)



Location of notification form



Supporting documents and certification



Supporting documents
Please upload your Test List here:

Add — No Attachments

File Upload

Notification Id: DV-2024-IVI-00248-1
Version: 1
Click Button to Select File: Choose file — No file chosen

Maximum attachment size is: 100Mb

Add

Certification
I, of [redacted] being the responsible person making this notification hereby certify that:

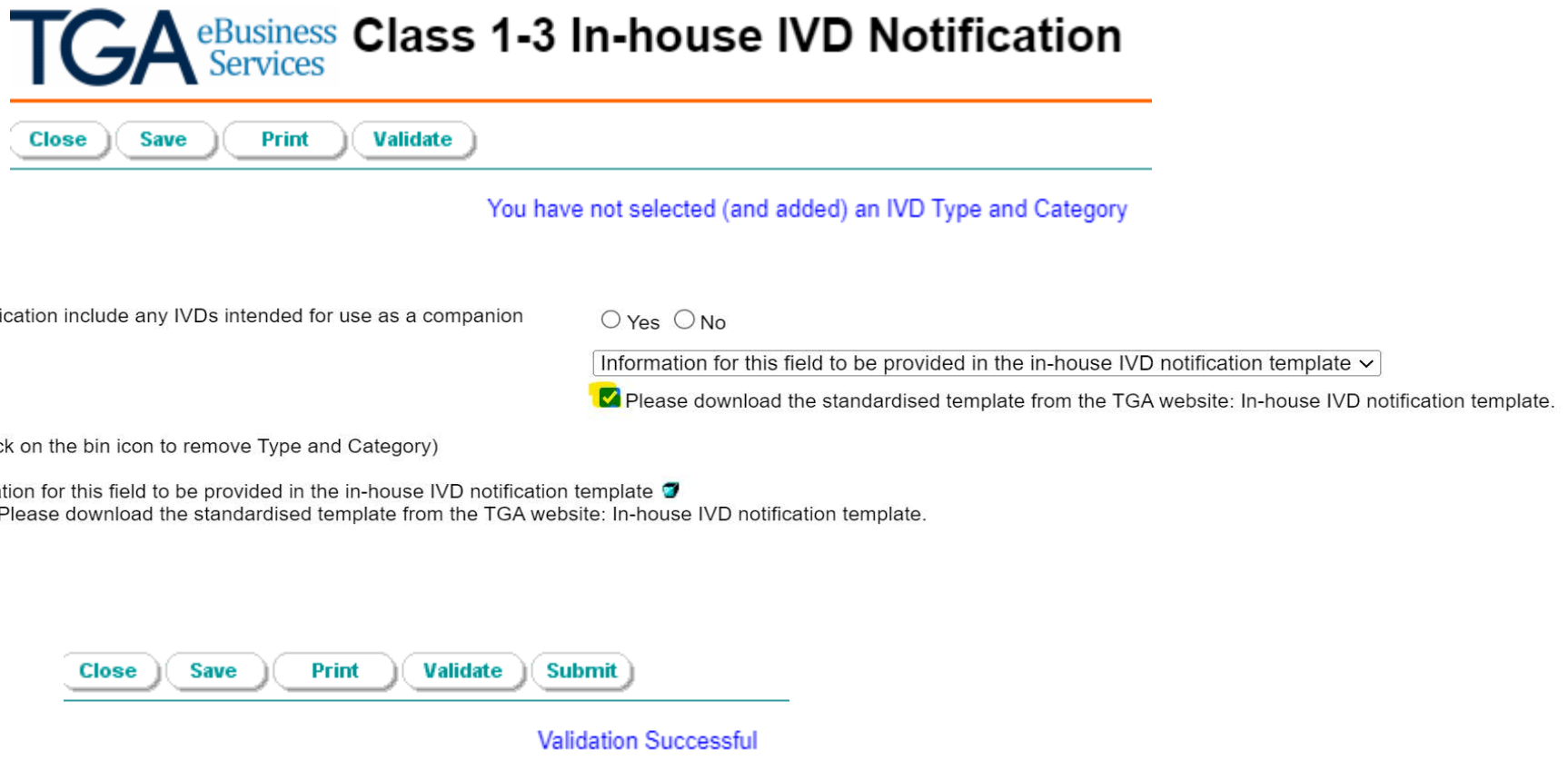
(a) the in-house IVD medical devices included in this notification are Class 1, 2 or 3 in-house IVD medical devices; and
(b) the Class 1, 2 and 3 in-house IVD medical devices comply with the essential principles and NATA accreditation requirements; and
(c) I have available information to substantiate that compliance with the essential principles and NATA accreditation requirements.
d) I acknowledge that any information I have provided in my notification of Class 1-3 in-house IVD medical devices may, upon request, be made available to the National Association of Testing Authorities (NATA).

In electronically submitting this notification to the TGA, I hereby certify that in relation to this IVD medical device the information given in this notification is current and correct.

I agree — (•) Yes ( ) No

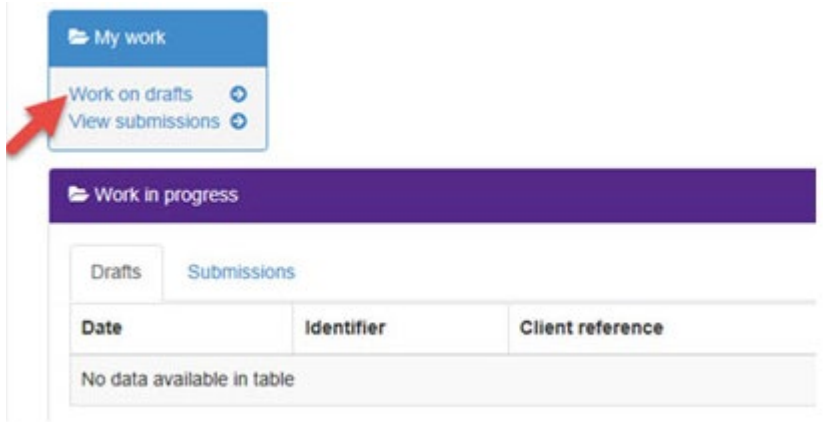
(End of Form)

Validating the form



Saving the form

- The form can be saved at any time without submission. To return to the draft form access the draft through ‘Work on drafts’.
- Once the form is completed, the template attached, and the form validated, just use the submit option.



Submitting the form

- The submit function will send the notification to the TGA and an invoice will be generated.
- The invoice can be viewed under the financial Tab in the Home page of the Portal OR will be sent directly to the Administrator (depending on the option selected at the creation of the Client).
- The current fee for a Class 1-3 in-house IVD notification is $1,155 (Fees and payments); this fee is indexed annually.

Some helpful tips for completing the form

- Some fields auto-populate, based on information in the laboratory's TGA Client details.
- The notification has a specific identifier in the format DV-20XX-IVI-XXXX-1: only one notification is required for each laboratory or laboratory network.
- Two options are available for QMS standard applied (ISO 15189 or ISO 17025)
- Select 'IVD Type' using the drop-down menu. Only one option is available. This directs the applicant to provide the IVD type information in the in-house IVD notification form (the Excel template).
- IMPORTANT: Use the ADD button to enable the validation of the form.
- Attach the completed (and mandatory) template under supporting documentation
- You need to agree to the declaration.

Post notification

- The TGA will review the notification and process the notification. An automated email will be sent to the contact person identified in the notification.
- If additional information is required, the contact person will receive an email requesting clarification or additional information.
- Submission of the notification satisfies the regulatory requirements for annual notification (when required) to the TGA.
- The information is stored in TGA records.

Transition timelines – new template and form

In-house IVD laboratories (with new tests to be notified)

- This refers to the new in-house IVD manufacturers or existing manufacturers that have developed new tests.
- You are required to use the newly introduced in-house IVD notification form and template for notification for the financial year by 1 July 2024.

Existing in-house IVD laboratories (i.e. previously notified)

- Please provide the completed template (with all the class 1 – 3 in-house IVDs developed and being supplied) prior to 30 September 2024. This can be sent to IVDs@health.gov.au as an email with the completed template attached. There will be no associated fee.

Planned date for introduction of new template and updated form - April 2024.
Guidance will be updated with link to the form Regulatory requirements for in-house IVDs

Questions?

natatgaivd@nata.com.au

ivds@health.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration