Australian Government
Department of Health
Therapeutic Goods Administration

Updating an existing Class 1-3 in-house IVD notification

How to navigate the online portal to create a new notification form for editing and submission

Version 1.0, March 2018

TGA Health Safety Regulation

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This guidance is for sponsors who are seeking to update their existing Class 1-3 in-house IVD notification which has been lodged with the TGA. Once any edits have been made to the form, it can then be submitted to become your current Class 1-3 in-house IVD notification.

TGA Business Services

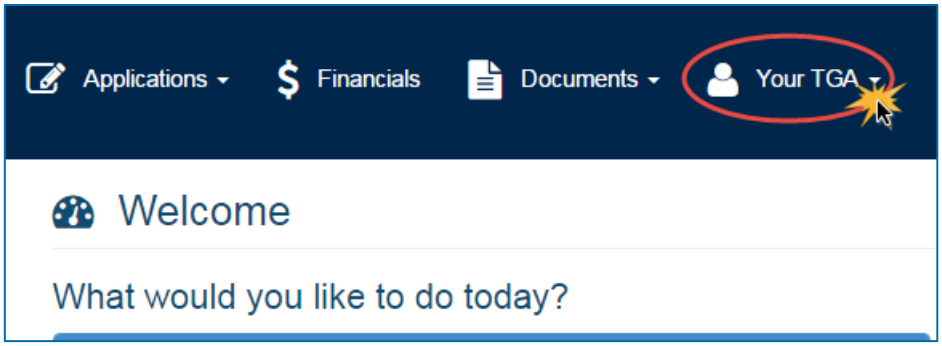
To vary the existing notification, you will need to login to the TGA Business Services portal.

- For help using TGA Business Services, including resetting your password, go to TGA Business Services – how to use this site.
- If you are experiencing issues with TGA Business Services site, please email ebs@health.gov.au or contact them on 1800 010 624.

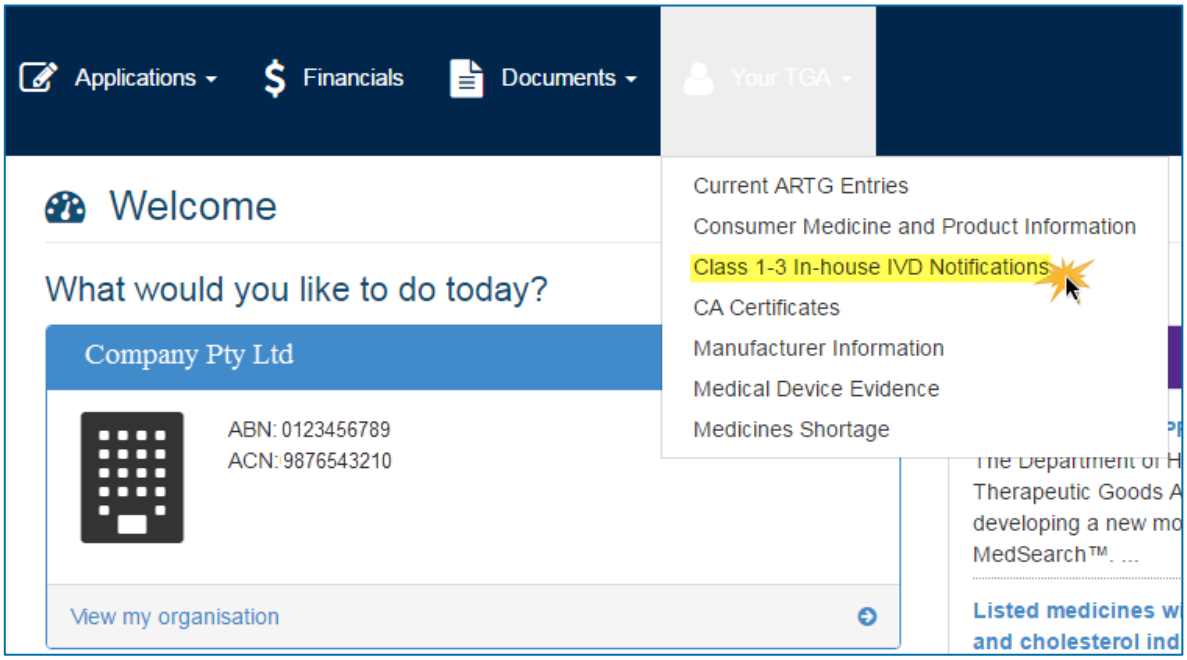
The Dashboard

Once you have logged in the portal, the dashboard will appear. At the top of the page there are three main menus: **Application**; **Documents**; and **Your TGA**. If you have a financial role, there is an additional **Financials** menu.

1. To access your existing notification, select the **Your TGA** menu.



2. From the drop down menu, select **Class 1-3 In-house IVD Notifications**.

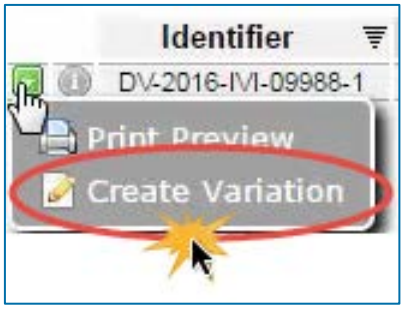


3. A list of all accepted notifications will appear within the user portal page.

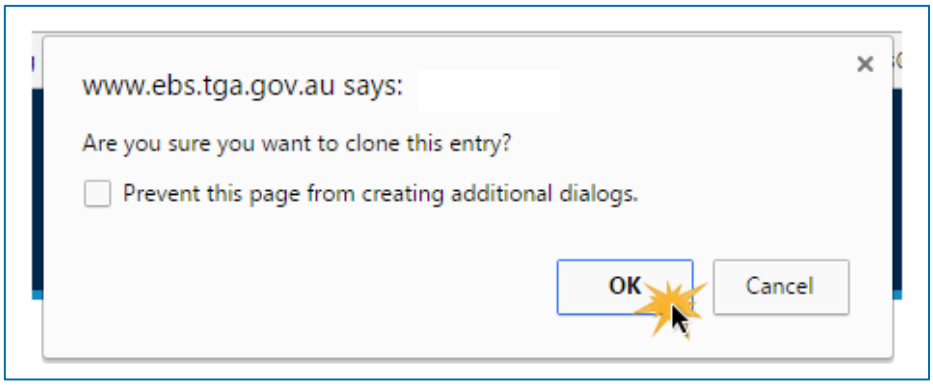
Creating a 'clone' of the existing notification

1. Find the notification that you wish to update. Click on the small grey, down pointing **arrow** icon that is located to the left of the notification identifier.

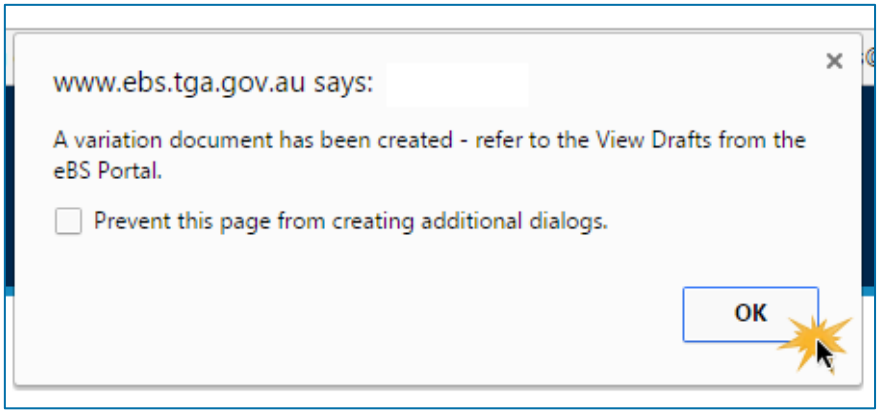
2. From the drop down menu, select **Create Variation**.



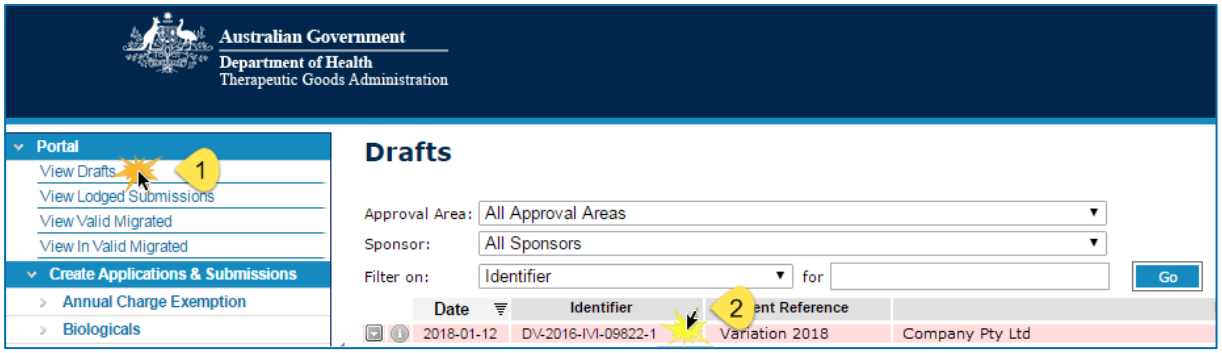
3. When the pop up box appears, click **OK** to initiate the cloning process. This may take some time.



4. An additional pop up box (see below) will appear, informing that the new notification application from has been created. Click **OK** to close the box.



5. Within the portal toolbar on the left hand side of the page, click on **View Drafts** (Step 1 in the picture below) to pull up all draft applications.



6. Click on the newly created draft notification (step 2 in the above picture) to open the form. Note that it will keep the original notification application identifier number.

Updating the draft notification application form

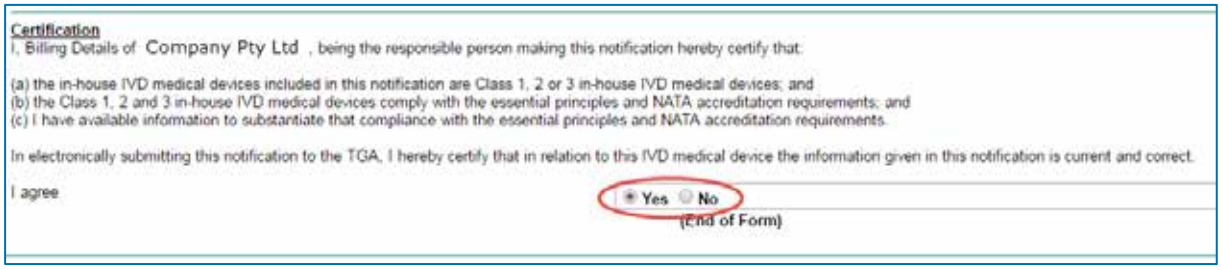
As the new draft notification form is a 'clone' of the existing notification, all details within the form will reflect the original notification, except for any attached documents – original attachments will not appear within the form.

7. To amend any or all details in the form, please refer to **Steps 3 to 13** of the Class 1-3 in-house IVDs: using the online application form guidance available on the TGA website.

At any stage you can save the notification form to your drafts by clicking the **Save** button at either the top or the bottom of the page.

Submitting your notification

8. Read the **Certification** at the end of page and select **Yes** if you agree.



You will have to agree to the certification in order to submit your notification.

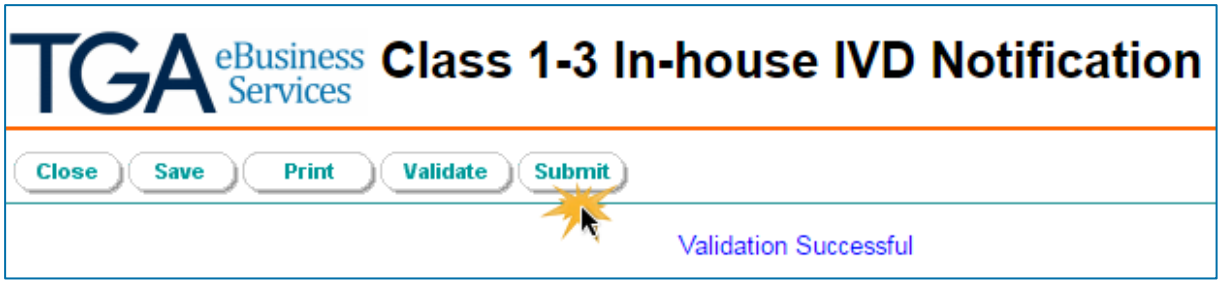
Note: Compliance with the NPAAC standard, *Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs)*, will be taken as compliance with the relevant essential principles for the safety and performance of a Class 1-3 in-house IVD medical device.

9. Click the **Validate** button at the bottom of the screen. This will run a check to see whether all mandatory questions have been answered.

Once the validation is complete, only someone with the submitter role can submit the application.

10. If you only have drafter rights there will be no **Submit** button at either the top or bottom of your screen. Click the **Save** button at either the top or bottom of the screen. Ask a person in your organisation that has submitter rights to verify the application and submit.

11. If you do have a submitter role click on the **Submit** button at either the top or the bottom of the screen.



We will only process your notification once we have received payment. When you submit the notification, an invoice will be automatically generated and will be visible if you have the financial role. Please note, we will not send you a paper copy of the invoice by post.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	March 2018

Therapeutic Goods Administration

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Reference/Publication #