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Department of Health and Aged Care

Office of the Gene Technology Regulator

OGTR Online Services Portal Form Guide – New Application to Change a Certification

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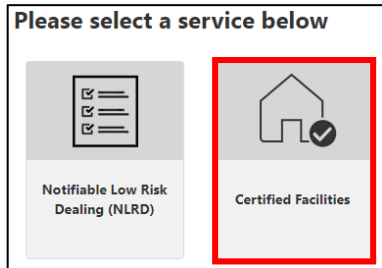
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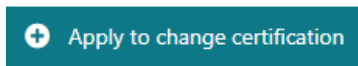
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Accessing the Forms relating to Certified Facilities

1. To access forms related to Certified facilities or existing Certifications, from the home page, select [Services] followed by the [Certified Facilities] service tile.



2. This will take you to the Certified Facilities dashboard.
 - Draft submissions will be visible on this page (the default view is five Submissions).
 - For accessing draft submissions, see the section [Accessing draft submissions, applications in progress or existing certifications](#)
3. To create a new form submission, select [Apply to change certification] to begin a new Change to Certification application.



Note: To apply for a new certification, see the relevant user guide on the [website](#).



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Form information

You can view information about the form, including timeframes, acknowledgements of receipt of applications and privacy on the “Information” page.

You can also view and/or print a “checklist” showing the information required to complete the form.

Checklist - Apply to change certification

To print this checklist you can click the 'print' button below and follow the instructions shown on your browser.

The following information will be required for you to complete the online application form.

Contact details for all change applications

- Application contact (person nominated as the contact for this submission)
- Contact Details of Facility contact (for PC2 Large Scale, PC3 or PC4 only)

All Variation types

- Details of relevant inspections
- Compliance with guidelines, including relevant existing exemptions or additional conditions

Variation: Extend the period of certification— nothing additional

Variation: Change the area covered by certification

- Details of changes (i.e. within existing area, adding/removing rooms)
- Removal of GMOs and details of decontamination (if applicable)
- Floor plan (depending on type of change)

Variation: Change the facility type or level of certification

- Proposed new facility level or type
- Details of anteroom(s)/airlock(s) (if applicable)
- Removal of GMOs and details of decontamination of area (if applicable)
- DNIR/DIR Licences affected by change in type or level.

Note: If DNIR/DIR licences being conducted in the facility require a variation, an application for variation should, at the least, have been submitted prior to submitting this application

Variation: Upgrade of the certification conditions to the current version of the guidelines

- Proposed version of the guidelines

Variation: Change the details in the facility description

- Proposed new facility description
- Changes in room numbers (if relevant)
- Floor plan (if room numbers have been changed)

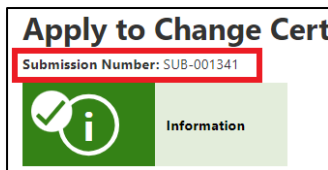
Variation: Request for a new exemption or change to an existing exemption/additional condition

- Details of request
- Rationale for request
- Suggested strategies for managing any risks that may arise

Print Close

Submission Number

Upon selecting [Next] from the Information page, your submission number will be generated and will appear above the left-hand menu. It can be noted down for reference, if needed. Once the number is generated, you can return to this draft submission at any time from the Draft Submissions dashboard.





Confidential Commercial Information (CCI)

At this stage, information that is, or may be subject to a CCI application cannot be submitted via the portal. If you believe your submission needs to include CCI, please contact the OGTR before completing the submission.

1. Select 'No' to the question "Will this submission contain any Confidential Commercial Information".

Confidential Commercial Information

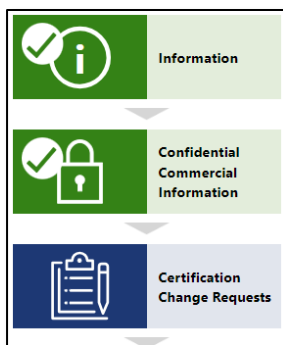
Will this submission contain any Confidential Commercial Information (CCI) *

Yes No

[Back](#) [Save and exit](#) [Save and continue](#)

2. Select [Save and Continue] to move to the "Certification Change Request" page.

Adding a new Certification Change Request



1. On the "Certification Change Request" page select the button [Add request].

Certification Change Request

Please add requests for the change of a certification using the 'Add request' button below. This submission requires at least one change request and cannot have more than 20 requests.

[Add request](#)

Type of Change

1. Search for the certification you wish to change by using the magnifying glass.

[Return](#)

Type of Change

Please select the certification you wish to change *

Click the magnifying glass to search

[Q](#)

Type the certification number into the search bar and press enter or click the magnifying glass to search. *Note: If you can see the certification in the list, click the checkbox to select it.*

Lookup records

Choose one record and click Select to continue

<input checked="" type="checkbox"/>	Certification No	Facility Level	Facility Type	Facility Description
<input checked="" type="checkbox"/>	Cert-5562	PC2	Laboratory	Room 1, Level 1, Building 1
<input type="checkbox"/>	Cert-5563	PC3	Facility	Room 2, Level 2, Building 2



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- The current details of the physical location for the facility will be prefilled. *Note: The details cannot be edited at this point; however, you can apply to change the details in the next step.*

Type of Change

Please select the certification you wish to change *

Click the magnifying glass to search

PC Level	Facility Type
<input type="text" value="PC2"/>	<input type="text" value="Laboratory"/>
Facility description	
<input type="text" value="Room 1, Level 1, Building 1"/>	
Instrument status	Expiry Date
<input type="text" value="Certified"/>	<input type="text" value="31/1/2029"/>

- Please tick all the changes to the certification you wish to apply for. At this point you can select as many variation types as necessary, except for 'Change the facility type or level of certification' and 'Upgrade the certification conditions to the current guidelines' which cannot be selected together.

Please tick the changes to the certification you wish to apply for: *

Variation

- Extend the period of certification
- Change the area covered by certification
- Change the facility type or level of certification
- Upgrade the certification conditions to the current guidelines
- Change the details in the facility description
- Request for a new exemption or to change an existing exemption or additional condition

- Select [Save and Continue] to move to the "Details of Change" page.



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Details of Change

Questions in this section will vary depending on instrument status of the selected certification, facility level and type, and the type of change selected. The number of tabs on the left-hand side will also vary for the same reasons.

The screenshot shows a web form titled "Certification Change Request". On the left is a navigation menu with four items: "Type of Change" (with a checkmark icon), "Details of Change" (with a document icon), "Inspection & Compliance" (with a checklist icon), and "Supporting Documentation" (with a document icon). The "Details of Change" section is active and contains two main parts. The first part is "Extend the period of certification", which states that no additional details are required for this variation. The second part is "Change the area covered by certification", which asks the user to tick one or more options: "Change within the existing area", "Rooms added to the certified area", and "Rooms removed from the certified area". Below these options is a text box for "Description of changes to area", with a note to include room numbers if applicable.

All mandatory questions in this section will be recognisable by the red asterisks at the end of the question.

This screenshot shows a specific question: "Change the details in the facility description". The question text is "New facility description:" followed by a red asterisk. Below it is a text input field. Below the field is another question: "Have there been any changes to the room numbers in the facility description:" followed by a red asterisk. This question has two radio button options: "Yes" and "No".

You might also find messages like the one below depending on your answers. If so, please follow the instructions within the message.

The screenshot shows a red-bordered error message box with a white 'X' icon. The text inside reads: "For this application to be submitted, the answer to this question must be 'Yes'. If you wish to discuss submitting an application that does not comply with this requirement, you must contact the OGTR by phone [1800 181 030](tel:1800181030) or email ogtr.CDES@health.gov.au".

Once all mandatory questions have been answered, you can select [Save and continue] to move to the next stage. Or you can select [Save and exit] to save the application as a draft and complete later.

The screenshot shows the bottom navigation bar of the form. It contains three buttons: "Back" on the left, "Save and exit" in the middle (highlighted with a red border), and "Save and continue" on the right.



Inspection and Compliance

1. On this page you will be required to respond to the inspection and compliance questions. If your answer to the second question is 'No', you will also be required to explain why.

Certification Change Request

[Return](#)

- Type of Change
- Details of Change
- Inspection & Compliance**
- Supporting Documentation

Inspection & Compliance

Has the facility been inspected against the relevant version of the certification guidelines? ^{*} [i](#)

Note: 'Relevant version' refers to the guidelines version under which the facility is to be certified following the change to the certification. This could be:

- guidelines under which the facility is currently certified,
- guidelines relevant to any requested new facility type/level, or
- an updated version of guidelines

Yes No

Does the facility comply with the relevant version of the certification guidelines? ^{*}

Please take into account any existing exemptions and/or additional conditions imposed in the current certification instrument (not applicable for requests to change the facility type/level).

Yes No

Details on the non-compliance of the relevant version of certification guidelines ^{*}

Please provide details on:

- Which requirements or conditions in the relevant guidelines are not met; and
- What strategies are being suggested to manage any risks that may arise, or reasons why it is considered that the requirement or condition is not necessary to achieve containment of the GMOs.

[Back](#) [Save and exit](#) [Save and continue](#)



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Supporting Documentation

Any additional attachments or information to support your application can be added here. In some instances, it will be mandatory to include documents such as an inspection report or floor plan with your application.

1. Select [Upload file]

Certification Change Request

[Return](#)

Supporting Documentation

Documentation to support your application

Any additional attachments to support your application can be uploaded here.

Files you upload must be:

- be in *.pdf, *.docx, *.xlsx, *.csv, *.pptx, *.png, *.tif, *.tiff, *.jpeg, *.jpg, *.gif, *.bmp, *.rtf, *.txt or *.zip
- each be no larger than 5MB
- in total be no larger than 50MB

[Upload file](#)

There are no folders or files to display.

Other information

Is there any other information that may assist the OGTR in making a decision about this application?

[Back](#) [Save and exit](#) [Save and continue](#)

2. Choose the files you wish to upload and select [Add files]. *Note: The 'overwrite existing files' is selected by default. This means that any files of the same name previously uploaded will be replaced.*

Add files

Choose files No file chosen

Overwrite existing files

[Add files](#) [Cancel](#)

3. The uploaded files will be added to the grid below.

File name	Modified
Capture.PNG (12 KB)	less than a minute ago

4. Select [Save and continue] to move to the next screen.

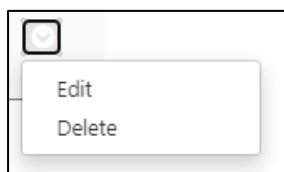


Apply to Change Certification - Grid

Once you have completed filling out your first request, you will return to the below screen. Here you will have the option to add another request. You may add up to 20 requests in one submission. You can also use the drop down to edit or delete requests prior to submission.

Certification No	Facility Level & Type	Change Type	Change Details
Cert-5562	PC2 Laboratory	Variation	Extend the period of certification

1. You can also use the drop down to edit or delete requests prior to submission.



2. Select [Save and Continue] to move to the “Attachment Summary” page.



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Attachment Summary page

This page will display summary information of all attachments that have been provided when the change request details were entered earlier.

1. Check that all relevant/required documents are attached.
 - a) If any of the details require editing, select the 'Edit...documentation' links circled below.

File name ↑	Modified
Floorplan.png (326 KB)	<u>2 minutes ago</u>

File name ↑	Modified
checklist.png (75 KB)	<u>less than a minute ago</u>

- b) Select the tick box at the bottom of the page, confirming that all necessary attachments have been uploaded.

I confirm that the necessary attachments have been uploaded *

2. Select [Save and Continue] to move to the "Contact Details" page.
3. At this point, the form will check to ensure that all mandatory information has been provided. The relevant page that is incomplete will be coloured amber and have an exclamation point indicated. You will need to navigate back through the form and provide required information in order to submit the form.

The form could not be submitted for the following reasons:

One or more mandatory fields or attachments are required.



**Certification
Change Requests**



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Contact Details

On the contact details page, you are required to enter the details of the nominated contact for the submission.

1. Click on the magnifying glass to open the search window

ogtr.applications@health.gov.au'"/>

2. In the new window, type a name, or part of a name into the search bar, and press enter or click the magnifying glass to search.



Reminder: To find someone in the list of contacts, they will need to already be recorded as an "Nominated Contact" in OGTR records. If a contact does not appear in the list, please follow the instructions on the page to have them added.

3. Once you have found the correct contact, tick the box next to their name and choose [Select] to add the contact.



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Choose one record and click Select to continue

<input checked="" type="checkbox"/>	Full name
<input checked="" type="checkbox"/>	Jamie Bloggs

4. Back on the "Contact Details" page, you will see the name of the contact is now showing in the Contact Name box.

Contact Name *

Please select the person from your organisation you would like to nominate as a contact for this submission.

Click the magnifying glass to search

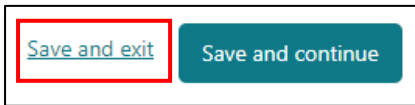
5. Select [Save and Continue] to move to the "Declaration" page.



Saving a draft submission

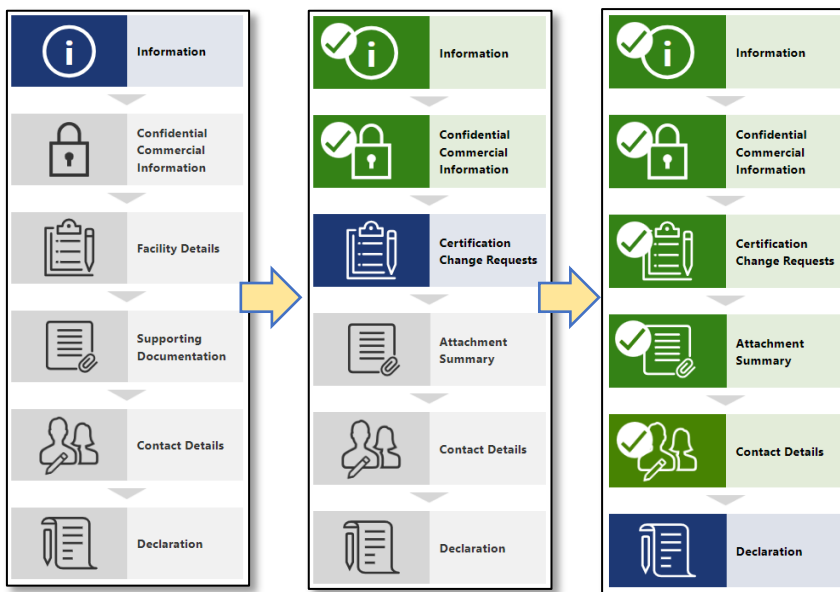
You will be unable to progress the form using [Save and Continue] until all required information on the page has been completed. The [Save and Exit] button can be used to exit a form with incomplete information on a page. Whatever details you have entered at that point will be saved, regardless of whether all required information has been entered.

When entering the request details, either selecting the [Return] button at the top of the left-hand side menu or [Save and exit] will save the information and return you to the “Certification Change Requests” tab of the main form. You will need to select [Save and exit] again to exit the submission.



When you access a draft submission, it will open from the last save point. The tabs in the form that are complete will be coloured green.

Note: You will need to navigate through the form using the [Save and Continue] buttons at the bottom of the screen, not by clicking on the chevron icons on the left-hand side of the page.



How the menu appears with no tabs marked as “completed”

How the menu appears when some tabs are marked as “completed”

How the menu appears when all tabs are marked as “completed” and the form is ready for submission.



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Declaration page

On the Declaration page, you will be required to make a legal declaration prior to submitting. You will have the opportunity to decide how to make this declaration, i.e. hard copy signature or a declaration checkbox.

Electronic declaration

1. To make a declaration electronically:

- a) select 'No' to the question "Do you need to have this application signed in hard copy?"

Do you need to have this application signed in hard copy? * ?
 Yes No

- b) Ensure the nominated contact shown in bold in the first paragraph is correct.

Note: In this example, that contact is **Jamie Bloggs**.

- c) Ensure that your name, as the person making the declaration, is shown in the declaration text.

Note: This may or may not be the same person as the Nominated Contact. In this example, the logged in user, who is the person making the declaration is **Jane Doe**

Nominated Contact

The nominated contact for this submission is **Jamie Bloggs**. A copy of the submission will be sent to the:

- Submitter of this form
- Nominated contact
- Organisation primary contact
- Organisation secondary contact

Person making the declaration

Jane Doe, declare that:

- I am a person authorised to submit this form;
- to the best of my knowledge, the information supplied on this form and any other attachment(s) is not false or misleading;
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the *Gene Technology Act 2000* and corresponding state law;
- by including my name on this form it is deemed to be my signature for the purpose of this form.

I agree to this declaration *

- d) To make the declaration shown on the screen, select the checkbox "I agree to this declaration".

Hard-copy declaration

2. To make a declaration in hard copy:

- a) select 'Yes' to the question "Do you need to have this application signed in hard copy?"

Do you need to have this application signed in hard copy? * ?
 Yes No

- b) Select [Print hard copy]



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c) A PDF copy of your form will be downloaded

1. Print and Sign
Click the print button below to generate a hard copy version of this reporting form. Please ensure that your browser allows for pop-ups in order to print the hard copy.

Print hard copy

Submission Number: SUB-001341

Creating submission document. Your download should start shortly

Desktop
Downloads

Today (4)
CERT submission SUB-001341

3. The PDF has information about the submission, such as the date the document was generated and the Submission ID.

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Document generated on:
26/02/2024 at 15:47 AEST/AEDT
Submission reference:
SUB-001341

4. The PDF must be signed and uploaded to submit the form.

Note: You must change the file name for the signed copy that you upload, this helps to ensure that the unsigned copy is not accidentally uploaded.

a) Ensure the PDF is signed in the necessary place and upload the document by selecting [Upload file].

I agree to this declaration. *

Signature:

Name:

Position:

Date:

2. Upload signed hard copy *

Files you upload must be:

- *.xls,*.xlsx,*.pdf,*.doc,*.docx,*.jpg,*.jpeg,*.tif,*.tiff,*.png, or *.zip format
- no larger than 5MB each
- no larger than 50MB in total

Upload file



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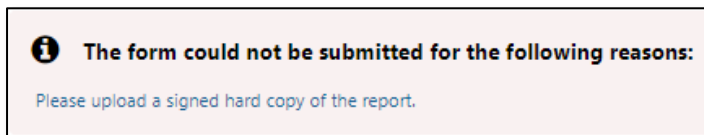
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Submitting the form

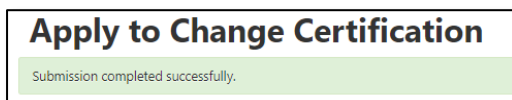
1. Once you have completed the declaration, select [Submit]



2. At this point, the form will check again to ensure that all mandatory information has been provided. If not, information will appear at the top of the page to indicate what is required.



3. If all form requirements are met and submission is successful, it will no longer be available on the “Draft submissions” tab of the “Certified Facilities” service page.



Following Submission

Following submission of a form, the following contacts will receive an acknowledgement of receipt email containing a copy of the PDF receipt:

- Primary contact
- Secondary contact (where one is recorded for the organisation)
- Nominated application contact
- Person that submitted the form

If any issues are identified with your submission, the OGTR will contact you. Additionally, if you need to contact the OGTR regarding your submission, your form submission email will contain a reference number you can refer to.

Following submission, each change request applications submitted (up to 20) will be assigned an OGTR identifier. This can be viewed on the “Applications in progress” tab of the “Certified Facilities” service page. See below for further guidance.

[Accessing draft submissions, applications in progress or existing certifications list](#)

Submission records are only used while a submission is being drafted. After submission the record will no longer appear on the “Draft submissions” tab in a service.

“Draft submissions” tab – shows forms that have not yet been submitted.

“Applications in progress” tab – shows submitted applications that have not yet been decided upon (includes the OGTR identifier and the decision due date).

Applications with the status of ‘Pending’ are those applications that still require manual data entry by the Application Entry Point Section of the OGTR prior to being assigned the status of ‘Submitted’.



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“Existing certifications” tab – shows certifications that are current and suspended, as well as surrendered, cancelled, or expired certifications from the past 5 years.

Information about using the dashboards can be found in the **“OGTR Online Services Portal User Guide”**.