



Guidance Note

For the submission of Applications to modify Certifications (i.e. Variation, Suspension, Lift of Suspension, Surrender and Transfer)

The OGTR requires certain information to process any applications to modify certifications (i.e. variation, suspension, lift of suspension, surrender and transfer). This guidance note indicates what information will assist efficient processing of an application request.

Applications to modify higher level certifications (PC2 Large Scale, PC3 & PC4) may require additional facility specific information. For further details please contact the Contained Dealings Evaluation Section of the OGTR via ogtr.cdes@health.gov.au or 1800 181 030.

Applicants can provide the following information either in the form of an email via ogtr.applications@health.gov.au or via hard copy letter to the office.

Letters must be signed by a person who is authorised by the instrument holder to make the request. If you are sending the request by e-mail, please either:

- attach a scanned image of a signed letter or authority, or
- if you are the person who is authorised to sign the request, include a statement in your e-mail stating that you are the person duly authorised to sign the request.

For all applications to modify certifications we require the following information:

- OGTR Certification number
- Applicant name
- Contact person for the secondary application

Variation Applications

There are 6 main reasons for applying to vary a certification. The information required is listed under each reason.

1. Extend the period of Certification

- Has the facility been inspected in last 12 months?
- Does the facility comply with the relevant guideline?

2. Change the area covered by the certification

- What are the proposed changes to room numbers of the certified area?
- If rooms are to be added:
 - Has the additional area been inspected?
 - Does the additional area comply with all the relevant guidelines?
 - Please provide a new floor plan indicating the proposed new boundary of the certified facility.

- If rooms are to be removed:
 - Have all GMOs from these rooms been decontaminated, destroyed, removed or appropriately stored?
 - Have the removed rooms been decontaminated?
 - Please provide a new floor plan indicating the proposed new boundary of the certified facility.

3. Change the facility type or level of certification

- What is the proposed new PC level and/or type of facility?
- Has the facility been inspected against, and can it comply with, the relevant guideline for the new facility type/level?
- If the level change is downward, have the higher risk group organisms been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*?
- If the change to the facility type precludes types of GMOs, have these organisms been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*?
- Are there any DNIR/DIR licences that are being undertaken in the facility that will be affected by the change to the type/level? If so, have these been appropriately varied? (Note: please ensure that any NLRDs are still being undertaken in an appropriate facility type/level as per the relevant *Gene Technology Regulations 2001* as amended).

4. Upgrade the certification conditions to the current version of the guidelines

- Has the facility been inspected against the relevant, current version of the certification guidelines by a competent person? (If so, please indicate the version number of the relevant, current version of guidelines)
- Does the facility comply with the relevant, current version of the certification guidelines?

5. Change the facility title

- What is the proposed new facility title?
- If there have been changes to the room numbers in the title then please provide a new floor plan indicating the new room numbering.

6. Request for a new exemption, change to an existing exemption, or imposition of an additional condition

- Please provide details supporting your request.
- Which of the current certification conditions are proposed to be removed or varied, or what additional conditions would you like to impose?
- What is the rationale for the proposed change to the conditions?
- Please provide details if the proposed change of conditions increases the likelihood of GMOs being inadvertently released from containment, or of persons being exposed to the GMOs.
- Please provide details if there are any risks to human health and/or the environment. How will these risks be managed?

Suspension and Lift of Suspension Applications

An application for suspension of certification must be made prior to any structural changes that will affect the containment of GMOs in the facility. The OGTR will make an assessment of the requested suspension and then issue an email or letter confirming the approval/refusal of the suspension application. This assessment can take up to a week, but may be longer in more complex cases. Please keep this in mind when proposing a date of effect for a suspension. Furthermore, please be aware that the conditions of certification continue to apply until you have received written approval of the suspension application from the Regulator or his delegate.

Following the completion of any structural changes, and prior to the recommencement of any work with GMOs in the facility, the suspension of the certification must be lifted by the Regulator. An application to lift the suspension is to be made by the certification holder. The facility must have been inspected by a competent person and found to comply with relevant guidelines. The OGTR will assess this request and issue an email or letter confirming the approval/refusal of the lift of suspension. Again, this assessment/approval process may take some time if there are complicating factors. Please note that no work with GMOs is to recommence in the facility until receiving written approval from the Regulator or his delegate.

1. Suspension Application

Before an application for suspension can be processed we require the following information to be supplied by the applicant:

- What is the reason for the proposed suspension?
- When do you wish the suspension to take effect?
- Has the facility been decontaminated?
- Have all GMOs been decontaminated, destroyed, removed or appropriately stored?
- Have (or will) the certification labels been removed/covered?

2. Lift of Suspension Application

Before an application to lift the suspension of a certification can be processed we require the following information to be supplied by the applicant:

- When do you wish the lift of suspension to take effect?
- Has anything changed during the period of suspension that might warrant a variation to the certification eg.
 - Change to the area covered by certification
 - Change to the facility title
 - Change to the version of the guidelines which applies to the certification

If so, also provide the information outlined on the previous page.

- Has the facility been inspected against the relevant version of the certification guidelines by a competent person? (If so, please indicate the version number of the relevant guidelines)

Please Note: This may be the version of the guidelines that was applicable at the time the certification was suspended or, the current version of the guidelines, if you wish to upgrade.

- Does the facility comply with the relevant guidelines, as specified above?

Surrender Applications

An organisation may request to surrender their certification when the facility is no longer required for work with GMOs. To process an application to surrender a certification we require the following information:

- Has the facility been decontaminated?
- Have all GMOs been decontaminated, destroyed, removed or appropriately stored?
- Have other authorizations, such as licences or NLRDs in this facility been appropriately varied or re-assessed by the relevant IBC?
- Have any other organisations or persons authorised to use the facility, who are not the certification holder, been advised of the intention for the certification to be surrendered?
- Have (or will) the certification labels been removed?
- When do you wish the surrender to take effect?

Transfer Applications

The holder of a certification and another organisation (transferee) may jointly apply to transfer the certification from the certification holder to the transferee. To process an application to transfer a certification, we require information to be supplied by both the certification holder and the transferee, including:

Certification Holder

- Has it been confirmed in writing that the certification holder would like the certification to be transferred to the transferee?
- Are there any DNIR/DIR licences that are being undertaken in the facility that may be affected by the transfer? If so, have these been appropriately varied or transferred?
- As there is no scope for transfer of NLRDs from one organisation to another, if any NLRDs are being conducted in the facility, a transfer of certification may require a new NLRD to be assessed and notified to the Regulator.

Transferee

- Has it been confirmed in writing that the transferee would like certification to be transferred to themselves?
- Has the facility been inspected and can the facility comply with the certification guidelines and any specific conditions currently imposed on the certification? (Note: please pay particular attention to the guidelines Part B “Obligations of the certification holder in respect of users of the facility”)
- Are there any DNIR/DIR licences that are being undertaken in the facility that may be affected by the transfer? If so, have these been appropriately varied or transferred?
- There is no scope for transfer of NLRDs from one organisation to another. Therefore, as a result of the transfer of a facility, any NLRDs done in the facility may require a new NLRD to be assessed and notified to the Regulator.
- Does the proposed transferee own the facility?
If NO, can the proposed transferee comply with any conditions which require:
 - upkeep of the physical containment attributes of the facility?
 - upkeep of fittings required by the conditions of certification?
 - the capacity to exclude persons from the facility?

- Does the proposed transferee own the equipment in the facility?
If NO, can the proposed transferee comply with any conditions which require testing, swupkeep and operation of the containment equipment?