# Guidance Note

## Minimum information required to submit a request 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 the minimum information that must accompany any request. An application without this minimum information will not be accepted.

Only persons authorised by the certification holder can submit an application to modify a certification. The OGTR maintains a list of such authorised persons for the certification holders. If the requesting person is not on this list, the application must state that they are authorised to request a modification.

Applicants can provide the following information either:

- in the online form available on the OGTR website;
- in an email (to ogtr.applications@health.gov.au); or
- by post (to OGTR, MDP 54, GPO Box 9848, Canberra, ACT, 2612).

Additional information may be requested in the course of assessment.

## Information required for all applications:

- Applicant name
- OGTR Certification number(s)
- Current physical containment (PC) level and facility type
- Contact person for the application

## Additional information required for variation applications

There are six categories of certification variation. The information required in an application for each variation category is listed below (note that an application can be for more than one variation category, with some limitations).

1. **Extend the period of Certification**
   - That the facility has been inspected against the relevant version of the certification guidelines by a suitably qualified/experienced person in the last 12 months.
   - That the facility complies with the relevant guidelines (taking into account any existing exemptions and/or additional conditions imposed in the current certification instrument).
2. **Change the area covered by the certification**
   - Proposed changes to the area or room numbers of the certified facility.
   - That the facility has been inspected against the relevant version of the certification guidelines by a suitably qualified/experienced person in the last 12 months *(Note: the inspection must be undertaken after any changes had been made to the area including addition and/or removal of rooms)*.

- That the facility complies with the relevant guidelines (taking into account any existing exemptions and/or additional conditions imposed in the current certification instrument).
- An updated floor plan indicating the proposed new boundary of the certified facility.
- Additional information if an area is to be removed:
  - That all GMOs from the area to be removed have been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.
  - That the area to be removed has been decontaminated.

**3. Change the facility type or physical containment level of certification**

- The proposed new PC level and/or type of facility
  *(Note: Facility level may only be decreased by way of a variation.)*
- That the facility has been inspected against the relevant version of the certification guidelines (for the new facility type/level) by a suitably qualified/experienced person in the last 12 months.
- That the facility complies with the relevant guidelines for the new facility type/level.
- That all GMOs that would no longer be permitted in the facility have been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.*
- That any DNIR/DIR licences that are being undertaken in the facility that will be affected by the change to the type/level, have been appropriately varied or transferred. (*Note: If an application for variation of DNIR/DIR licences has been submitted to the OGTR, this is sufficient for the purposes of this application.)*

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

- That the facility has been inspected against the relevant version of the certification guidelines by a suitably qualified/experienced person *(Note: the 'relevant version refers to the guidelines version under which the facility will be certified following the requested upgrade to the conditions)*.
- That it complies with the relevant version of the guidelines (taking into account any existing exemptions and/or additional conditions imposed in the current certification instrument).

**5. Change the facility description**

- Provide details of the proposed new facility description.
- If there have been changes to the room numbers in the facility description, provide an updated floor plan indicating the new room numbering.

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

Provide details supporting your request, including:

- The current certification conditions that are proposed to be removed or varied.
- The rationale for the proposed change to the conditions.
- The details of the proposed strategies to manage any risks that may arise.

## Additional information required for 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 assigned delegate.

The following information is required to be supplied:

- The reason for the proposed suspension.
- The proposed date of effect of the suspension.
- That all GMOs have been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs.*
- That the facility been decontaminated.

## Additional information required for lift of suspension applications

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 suitably qualified/experienced 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. 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 lift of suspension. Please note that no work with GMOs is to recommence in the facility until receiving written approval from the Regulator or assigned delegate.

The following information is required to be supplied:

- The proposed date of effect of the lift of suspension.
- If anything has changed during the period of suspension that might warrant a variation to the certification e.g.
    - Change to the area covered by certification
    - Change to the facility description
    - Change to the version of the guidelines which applies to the certification

  also provide the information outlined under the relevant heading in the section above ("Additional information required for variation applications").
- That the facility has been inspected against the relevant version of the certification guidelines by a suitably qualified/experienced person in the last 12 months (*Note: The facility should be inspected as close as practicable prior to submission of lift of suspension request).*
- That the facility complies with the relevant guidelines (taking into account any existing exemptions and/or additional conditions imposed in the current certification instrument).

## Additional information required for surrender applications

An organisation may request to surrender their certification when the facility is no longer required for work with GMOs. The following information is required to be supplied:

- The proposed date of effect of the surrender.
- That all GMOs have been removed, destroyed or appropriately stored as per the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs*.
- That the facility been decontaminated.

## Additional information required for 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.

The following information is required from each party:

Certification Holder

- That they would like the certification to be transferred to the transferee.

Transferee

- That they would like the certification to be transferred to their organisation.
- That the facility has been inspected against the relevant version of the certification guidelines by a suitably qualified/experienced person in the last 12 months.
- That it complies with the relevant certification guidelines (taking into account any existing exemptions and/or additional conditions imposed in the current certification instrument).
- 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, upkeep and operation of the containment equipment?