



**Australian Government**

**Department of Health and Ageing**

**Office of the Gene Technology Regulator**

# **Explanatory Information**

# **Guidelines for Certification of Physical Containment Facilities**

1 July 2007

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## Definitions

Unless defined otherwise in this document, words and phrases used in this document have the same meaning as in *Gene Technology Act 2000* (the Act) and the *Gene Technology Regulations 2001*.

Words in the singular include the plural and words in the plural include the singular. Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

Where a word in the text is **bolded**, it indicates that the word has been defined (see below).

**anteroom** An area or room between a pair of doors through which access is gained to the work area inside a **facility**.

The **anteroom** must not be used for performing any procedures with **GMOs**.

**dealings or deal with** In relation to a **GMO**, means the following:

- (a) conduct experiments with the **GMO**;
- (b) make, develop, produce or manufacture the **GMO**;
- (c) breed the **GMO**;
- (d) propagate the **GMO**;
- (e) use the **GMO** in the course of manufacture of a thing that is not the **GMO**;
- (f) grow, raise or culture the **GMO**;
- (g) import the **GMO**;
- (h) transport the **GMO**;
- (i) dispose of the **GMO**;

and includes the possession, supply or use of the **GMO** for the purposes of, or in the course of, a **dealing** mentioned in any of the paragraphs (a) to (i).

**DIR** **Dealing** involving intentional release of a **GMO** into the **environment**.

**DNIR** **Dealing** not involving intentional release of a **GMO** into the **environment**.

**environment** Includes:

- (a) ecosystems and their constituent parts;
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas.

**facility** The whole of the space that is to be certified by the Regulator to a specific level of containment.

**GM** Genetically Modified

**GMO** Genetically Modified Organism.

**NLRD** Notifiable Low Risk **Dealing**

# PART 1 – INTRODUCTION

## Governing legislation

- 1.1 The Commonwealth Act and the Commonwealth regulations, together with corresponding state legislation, provide the legislative foundation for Australia’s national scheme laws for the regulation of gene technology.
- 1.2 The objectives of the national scheme laws are to protect the health and safety of people, and to protect the **environment**, by identifying risks posed by, or as a result of, gene technology, and by managing those risks by regulating certain **dealings** with **GMOs**.
- 1.3 The national scheme laws prohibit **dealings** with **GMOs**, other than a limited range of permissible, authorised **dealings**. They establish a statutory officer, the Gene Technology Regulator (the Regulator), whose role is to administer these laws. Part of the Regulator’s role includes responsibility for promoting compliance with the laws, and prosecuting non-compliance.
- 1.4 Under the provisions of the legislation, certain **dealings** with **GMOs** must be conducted within physical containment **facilities**.
- 1.5 Section 90 of the Act provides for the Regulator to “issue technical or procedural guidelines about the requirements for the certification of **facilities** to specified containment levels”. Containment levels in these guidelines are referred to as ‘physical containment levels’ in the certification guidelines and are aligned as closely as possible to the physical containment levels described in AS/NZS 2243.3<sup>1</sup>.
- 1.6 Section 84 of the Act provides for the Regulator to issue a written instrument certifying a **facility** to a specified containment level provided the **facility** meets the requirements specified in the guidelines issued under section 90.
- 1.7 Section 86 of the Act provides that the certification of a **facility** is subject to:
  - any conditions imposed by the Regulator at the time of certification;
  - any conditions imposed by the Regulator in varying the certification under section 87 after certification;
  - any conditions imposed by the regulations.

## Purpose of certification

- 1.8 The purpose of certification is to satisfy the Regulator that the containment **facility**:
  - prevents release of **GMOs** into the **environment**; and
  - protects persons outside the **facility** from exposure to **GMOs**; and
  - protects the safety of people working with **GMOs** inside the **facility**.

## Certification and dealings with GMOs

- 1.9 A licence for a **DNIR** will require the **dealing** to be conducted in a **facility** certified by the Regulator against the relevant certification guidelines for the physical containment level and **facility** type necessary to contain the dealing.
- 1.10 **Dealings** that are **NLRDs** mentioned in Part 1 of Schedule 3 of the regulations, as in force from 1 July 2007, must be undertaken in a facility certified by the Regulator to at least PC level 1.

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<sup>1</sup> Australian/New Zealand Standard 2243.3 *Safety in laboratories Part 3: Microbiological aspects and containment facilities*.

- 1.11 **Dealings** that are **NLRDs** mentioned in Part 2 of Schedule 3 of the regulations, in force from 1 July 2007, must be undertaken in a facility certified by the Regulator to at least PC level 2.
- 1.12 Sometimes, some aspects of **DIRs** may also be required to be conducted in certified **facilities**.
- 1.13 Guidance on the types of **dealings** that can be conducted in the various PC levels and **facility** types is contained in the *Guide to Physical Containment Levels and Facility Types*, available from the OGTR website <www.ogtr.gov.au> or from the OGTR.

### **Purpose of the certification guidelines**

- 1.14 The certification guidelines contain the requirements that the Regulator takes into account when certifying different types of **facilities** to specified containment levels.

### **Limits to coverage of the certification guidelines**

- 1.15 The certification guidelines only include requirements that contribute to achieving the objectives of the Act with respect to **dealings** with **GMOs** that require containment in physical containment **facilities**. They do not provide comprehensive coverage of laboratory design and construction.
- 1.16 For guidance on whether there is a need to comply with any other regulatory requirements, certification holders should refer to all other relevant legislation applicable in the jurisdiction in which the **facility** is located.
- 1.17 For further guidance on the comprehensive details of laboratory design and construction, biological safety, laboratory safety, and broader occupational health and safety issues, certification holders may like to refer to AS/NZS 2982.1<sup>2</sup> and AS/NZS 2243.3.

### **Relationship between the certification guidelines and AS/NZS 2243.3**

- 1.18 The requirements in the certification guidelines are intended to harmonize as closely as possible with AS/NZS 2243.3, but they have been drafted in a style that enables enforcement under the Act, and provisions have been included for the purposes of administration of the certification process under the Act.
- 1.19 The certification guidelines for each **facility** type and PC level contain the minimum set of requirements that the Regulator considers the physical aspects of a **facility** must meet to fulfil the objectives of the Act with respect to the physical containment of **GMO dealings**.
- 1.20 Therefore, many of the physical requirements detailed in AS/NZS 2243.3 have not been included in the Regulator's certification guidelines as requirements or in the usual conditions of certification. This includes a long list of requirements for **facility** construction picked up in AS/NZS 2243.3 by reference to AS/NZS 2982.1.
- 1.21 AS/NZS 2243.3 is specifically intended for work with micro organisms in laboratories. The Regulator may issue guidelines for **facility** types not covered by AS/NZS 2243.3, particularly for the containment of **GMOs** that are not micro organisms.
- 1.22 It is not intended that compliance with the requirements of the Regulator's certification guidelines would imply that a **facility** is compliant with AS/NZS 2243.3.
- 1.23 Likewise, compliance with the requirements of AS/NZS 2243.3 does not circumvent the need to apply to the Regulator for certification. However, any documentation or evidence of compliance with requirements of AS/NZS 2243.3 that relate to a requirement in the certification guidelines for a relevant **facility** type and PC level may be considered as part of

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<sup>2</sup> Australian New Zealand Standard 2982.1 - *Laboratory design and construction Part 1: General requirements*.

the process of evaluating an application for certification. Applicants who have such documentation or evidence are welcome to discuss their application with the OGTR before submitting it.

### **Compliance with other regulatory agencies**

- 1.24 Where a containment **facility** is jointly regulated by another regulatory agency, e.g. the Australian Quarantine and Inspection Service, there is potential for confusion about compliance with multiple regulatory requirements and a conflict of requirements.
- 1.25 As far as is practicable, the requirements in the certification guidelines aim to harmonize with those of other agencies. However, different legislative requirements make it necessary for each agency to approve the **facility** to meet the objectives of their respective governing legislation.
- 1.26 Differing administration of the regulatory agencies may also result in different floor areas, rooms or buildings being approved rather than an exact, one to one, corresponding approval.
- 1.27 In the event of any apparent or real conflict of requirements, applicants are welcome to contact the OGTR to discuss the situation prior to making the application. Alternatively, the application can include information about the conflict and any proposal to manage any risks associated with such a conflict.

### **Compliance with other legislation**

- 1.28 Where there is a conflict between the requirements of the certification guidelines and other general legislative requirements, for example the requirements of State legislation in State in which you are operating, the matter should be discussed with the OGTR.

### **Changes to the structure of the certification guidelines from 1 July 2007**

- 1.29 Certification guidelines issued on or after 1 July 2007 consist of:
  - definitions specific to each guideline;
  - the requirements, issued pursuant to section 90 of the Act, which must be met prior to certification;
  - the usual conditions that are likely to be applied to a **facility** that is certified against the requirements;
  - a guide to the behaviour of personnel conducting **dealings** in certified **facilities**; and
  - a list of the Australian / New Zealand standards referenced in the requirements and conditions.
- 1.30 More detail on the application of each part of the new structure is provided in the following sections of this document.

## PART 2 – HOW TO GET A FACILITY CERTIFIED

### Applying for certification

- 2.1 Under section 83 of the Act a person may apply, in writing, to the Regulator for certification of a **facility**. Application proformas have been prepared for this purpose and these can be obtained from the OGTR or downloaded from the OGTR website.

### Choosing the physical containment level and facility type

- 2.2 The certification guidelines establish four levels of containment, listed here in ascending order of the stringency of containment requirements, reflecting the level of risk:
- Physical Containment Level 1 (PC1)
  - Physical Containment Level 2 (PC2)
  - Physical Containment Level 3 (PC3)
  - Physical Containment Level 4 (PC4)
- 2.3 These levels are intended to align as closely as possible with the Physical Containment Levels described in Section 3 of AS/NZS 2243.3.
- 2.4 There are also several types of **facility** designed to contain different types of organisms and **dealings** (micro organisms, plants, animals, etc).
- 2.5 Applicants will be required to indicate on the application form the PC level and the type of **facility** to be certified. The PC level and **facility** type will dictate which inspection report checklist, if any, should be completed and submitted with the application.
- 2.6 The *Guide to Physical Containment Levels and Facility Types* provides details of the PC levels in relation to the regulation of gene technology and describes the types of **dealings** that can be done in each **facility** type. This guide is available from the OGTR website <[www.ogtr.gov.au](http://www.ogtr.gov.au)> or from the OGTR.

### Confidential commercial information

- 2.7 The Act provides that a person may apply to the Regulator for a declaration that specified information is confidential commercial information (CCI) for the purposes of the Act.
- 2.8 The Act sets out the matters about which the Regulator must be satisfied before declaring that certain information is confidential commercial information.
- 2.9 The applicant must satisfy the Regulator that the information specified in the application is:
- a trade secret; or
  - any other information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
  - other information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking, and if it were disclosed, could unreasonably affect the person, organisation or undertaking.
- 2.10 The Regulator may refuse to declare that the information is confidential commercial information if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.
- 2.11 Details of **facilities** that have been certified are not included on the public Record of **GMO Dealings** and **GM Products**. Details of **facilities** would normally be only provided to a third party in response to an application under the Commonwealth *Freedom of Information Act 1982*.

- 2.12 Each piece of information (for which the organisation seeks protection) must be detailed in an application for a declaration of CCI and the criteria detailed in the Act must be met for each piece of information. An application for the declaration of CCI may be downloaded from the OGTR website.

### **Requirements to be met before the application for certification can be approved**

- 2.13 A **facility** may be certified if the Regulator is satisfied it meets the containment requirements set out in the certification guidelines. The specific requirements for the certification of each **facility** type at each different PC level are set out in individual guidelines.
- 2.14 All **facilities** must be inspected to assess compliance with the requirements for certification and to assess the ability to comply with the usual conditions that will be applied to the certification.
- 2.15 Staff of the OGTR, or an independent expert, will usually conduct the inspection of the following **facilities** for the Regulator, prior to certification:
- PC1 and PC2 Large Scale facilities; and
  - all PC3 and PC4 facilities.
- 2.16 Inspection of all other **facilities** must be conducted by someone qualified to assess compliance with the requirements for certification. The inspection may be conducted by the applicant or by an independent person.
- 2.17 Inspection checklists are not mandatory for all **facility** types. They must be submitted with applications for PC1 Large Scale facilities, PC2 Large Scale facilities, and all PC3 and PC4 facilities.
- 2.18 For all others, checklists may be used if convenient. Proforma checklists have been prepared for each PC level/**facility** type and are available from the OGTR or can be downloaded from the OGTR website.
- 2.19 Applicants may choose to use a different format for inspection reports for the **facilities** that require submission with the application, but the inspection report must address each of the requirements for certification of the relevant PC level/**facility** type.

### **Floor plans**

- 2.20 Floor plans or diagrams of the layout of the **facility** must be submitted with all applications for certification. If certification of a whole building, or the majority of a building, is being sought, the entire floor plan will be required. If certification is sought for one or more rooms within a larger area, the plan must show the boundary of the **facility** (doors and walls) as well as any adjoining corridors and their doors. If there are any lifts or stairs in the **facility**, or adjoining areas/corridors, they must be shown on the plan as they may have a significant bearing on the approval of the application.
- 2.21 When applying for certification of **facilities** that require **anterooms** (arthropod, animal and plant containment **facilities**) the **anteroom(s)** must be clearly indicated. If an adjoining corridor or another certified or non-certified room is proposed to perform the function of an **anteroom**, the floor plan must show all doors, lifts, stairs, and any other relevant details that may compromise the functioning of the corridor or room as an **anteroom**.

### **What to do if the requirements cannot be met or do not apply to the facility**

- 2.22 There may be circumstances where a specific requirement or proposed usual condition for a PC level/**facility** type may not be applicable. Where **facility** design or proposed work practices can be shown to provide the necessary containment or risk management for the **dealings** to be conducted in that **facility**, a request for an exemption from the requirement or

condition in question may be made on the application form. Applicants are welcome to discuss the proposal with the OGTR prior to completing the application.

- 2.23 A request for exemption from a particular requirement or condition must be supported with information explaining the reason for the request and the proposed risk management strategy that will apply in place of the requirement for which the exemption is requested. If the Regulator approves the request, conditions may be imposed on the certification relating to the exemption. Such conditions might, for example, restrict the types of **dealings** that can be conducted in the **facility**, or include the imposition of additional physical containment and/or procedural requirements.

### **Capacity to comply with certification conditions**

- 2.24 Once an application for certification is approved, the certification instrument will include the conditions imposed on the **facility**. These conditions must be complied with at all times during the period of certification in order to maintain the certification.
- 2.25 The usual conditions that will be applied to a **facility** type/PC level are annexed to the specific guidelines for the certification of each PC level/**facility** type.
- 2.26 On the application form there is a section that asks if the applicant has the capacity to comply with the usual certification conditions that will be applied to **facilities** of the type being applied for. It is not possible to comply with many of these conditions prior to the approval of the certification, particularly if the **facility** is not already operating as a physical containment **facility**. However, applicants are expected to have procedures in place to enable compliance once the certification is approved.
- 2.27 As in the case of the certification requirements, there may be some conditions that are not necessary or appropriate to the particular **facility** design or proposed **dealings**. Applicants are able to provide information on the application form explaining how the necessary containment or risk management for the **dealings** to be conducted in that **facility** will be provided to manage any risks posed by non-compliance with the condition.
- 2.28 This information will be taken into account in evaluating the application and in determining the conditions that will be imposed on the certification, if approved.
- 2.29 Applicants are welcome to discuss any questions they have about certification conditions with the OGTR.

### **Assessment of applications for certification of facilities**

- 2.30 Applications for certification of **facilities** are considered by the Regulator. The regulations provide that these applications are decided within 90 working days of receipt of the application, unless the period is extended because the Regulator has sought additional information from the applicant.
- 2.31 When applications for certification of PC1 Large Scale facilities, PC2 Large Scale facilities, PC3 facilities or PC4 facilities are made, the Regulator usually requires inspection by the OGTR or an independent expert. These inspections are conducted prior to certification.

### **Notification of certification**

- 2.32 If the application is successful, the Regulator will issue a certification instrument that includes details of the **facility**, the period for which the **facility** is certified and the conditions of the certification.
- 2.33 If the application is unsuccessful, the Regulator will write to the applicant detailing the terms of the decision, the reasons for the decision and a statement setting out the applicant's review rights with respect to the decision.

## PART 3 – HOW TO MAINTAIN A CERTIFICATION

### Imposition of conditions

- 3.1 Conditions are imposed on **facilities** by the Regulator at the time of certification, pursuant to section 86 of the Act. The condition clauses that can be expected, in most cases, to be included in the certification instrument are attached to the guidelines for each **facility**.
- 3.2 The conditions relating to the **facility** structure and fittings are similar to the requirements that must be met prior to certification. The wording is generally altered to reflect the need to maintain the **facility** and fittings during the period of certification.
- 3.3 There are also additional, ‘general’ conditions that pertain to the administration of the certification process under the Act.
- 3.4 From 1 July 2007 a new section of the conditions has been added detailing obligations of the certification holders in respect of the users of the **facilities**. These obligations include:
  - provision for certification holders to control access to a **facility**;
  - provision for the Regulator to direct certification holders to exclude a person or class of person from a **facility**;
  - conditions covering the authority of the certification holder, if not the owner of a **facility**; and
  - a condition specifically allowing the Regulator or a person authorised by the Regulator to be able, at all reasonable times, to enter a **facility** for the purposes of auditing or monitoring the conditions applying to a **facility** and any **dealings** being conducted in a **facility**.

### Compliance with conditions of certification

- 3.5 The conditions of certification must be complied with at all times during the period for which the **facility** is certified. In all cases it is the responsibility of the holder of the certification to ensure compliance with the conditions of certification.
- 3.6 Prior to any significant structural changes that will affect the containment of **GMOs** in the **facility**, the applicant must either:
  - request a suspension of the certification, in writing, from the Regulator; or
  - for PC1 or PC2 facilities, request a variation to the conditions of certification in writing, from the Regulator, to allow **dealings** to continue in a part of the **facility** unaffected by the structural changes. Such a variation may, for example, temporarily partition the **facility** to provide containment for **GMOs** at one end while the other end is being modified.
- 3.7 Before a suspension of the certification can be lifted, or the variation reversed, the **facility** must be inspected by a person qualified to assess the **facility’s** compliance with the conditions of certification. **Dealings** with **GMOs** must not recommence in a **facility** which has its certification suspended until the Regulator has lifted the suspension by notice in writing.
- 3.8 In the case of a variation, as described in the example above, **dealings** must not be conducted in a part of the **facility** that has been excluded from the **facility** by variation, until the Regulator approves a further variation to allow the resumption of **dealings** in that part of the **facility**.
- 3.9 For PC3 & PC4 **facilities** an inspection by officers of the OGTR or an independent expert must be conducted after the completion of work on the **facility** prior to lifting of a suspension.

## Behavioural requirements

- 3.10 From 1 July 2007 a new clause has been included in the conditions of certification to provide for the Regulator to be able to require the certification holder to exclude a person, or a class of person, from a **facility**, if the person, or class of person:
- has behaved, or is behaving, in a manner which has caused, or which may cause, **GMOs** to escape from a **facility**; or
  - has behaved, or is behaving, in a manner which has exposed, or exposes, other persons in a **facility** to a **GMO** in circumstances where the exposure causes, or is capable of causing, a threat to the health and safety of those other persons.
- 3.11 Exclusion of a person, or class of person, from a **facility** is a measure directed at ensuring that the ongoing containment capacity of the **facility** or the safety of others in the **facility** is not compromised by the behaviours of persons conducting **dealings** in the **facility**, whether **NLRDs** or **DNIRs**. This is recognition by the Regulator that inappropriate behaviour is just as likely to lead to the escape of **GMOs** as is any inadequate physical or structural feature of a **facility**. The Regulator's ongoing capacity to require exclusion of a person from a **facility** is founded on this concern.
- 3.12 However, for the purposes of determining whether or not a person, or class of person, has behaved in a manner which compromises containment or the safety of others in a **facility**, the Regulator may give consideration to the particulars of any behaviour which has compromised, or may compromise, the containment capacity of the **facility** or the safety of its occupants. This consideration may be given whether or not the specific behaviour in question is covered in the 'Behavioural Requirements' attached to the conditions.
- 3.13 This is because the Regulator accepts and recognises that:
- scientific researchers typically behave in a responsible manner which generally will not compromise the capacity of a **facility** to contain **GMOs** or the safety of others in the **facility**; and
  - behaviour which differs from that recommended in the training will not always be a threat to others or to the containment of the **GMOs**; and, conversely,
  - behaviour which threatens the containment of the **GMOs** or the safety of others will not always be able to be listed in a finite set of behaviours.
- 3.14 Exclusion of a person, or class of person, may not necessarily affect the ongoing authority of an organisation or a licence holder to continue to conduct **dealings** authorised under the Gene Technology Act 2000. The **dealings** may continue to be conducted by other persons authorised to enter the **facility**. For example, in the case of a licence, if a person covered by the licence is excluded it would be appropriate for an organisation to nominate another person covered by the licence.
- 3.15 Note also, that in cases where behaviour leads to concerns for the effective containment of the **GMOs**, ongoing admission of a person to a **facility** may be restricted, subject to conditions imposed by the Regulator.
- 3.16 The Regulator will generally not require the certification holder to exclude, or impose conditions of entry on, a person, or class of person, without giving the certification holder notice and an opportunity to comment on why the person, or class or person, should not be excluded, or have conditions imposed on their entry, unless the immediate exclusion of the person, or class of person, is necessary to protect the health and safety of people or to protect the **environment**.
- 3.17 It is also a condition of the certification that the certification holder ensure that access to a **facility** is confined to persons who are trained in a specific set of behaviours appropriate to the **facility** itself and the **dealings** being conducted in that **facility**.

- 3.18 It is a matter for the certification holder to determine whether or not the person already has adequate training in the behaviours as they apply to that **facility**. For example, a person covered by a licence may have already had the relevant training by the licence holder pursuant to a condition in the licence. If satisfied that this training meets the certification obligation, the certification holder may accept a signed and dated statement, stating that they have the relevant training, from a person as a record that the training has been undertaken. Where the relevant training has not occurred, the person must undergo training before being admitted into the **facility** to undertake **dealings**. The certification holder or other suitably qualified person may provide the relevant training.

### **Variation of certification conditions requested by the certification holder**

- 3.19 A certification holder may request a variation to the certification in writing (hard copy, e-mail or fax).
- 3.20 A common reason for seeking a variation is when **facilities** are renovated, as discussed above. Other common reasons are when rooms are to be added or removed from suites of rooms covered by a single certification, when there is a change to the name of a certified **facility**, or when there is a change in the nature of the **dealings** which may result in different work practices.
- 3.21 Certification holders are welcome to contact the OGTR to discuss what is required before applying for a variation. Alternatively, the written application for the variation can include information about the proposed changes affecting compliance with the conditions.
- 3.22 In cases where renovations are undertaken or changes have been made to the room configurations to be covered by the certification, it is most likely the OGTR will need to see revised floor plans. A new inspection report checklist may be requested for PC1 Large Scale facilities, PC2 Large Scale facilities, PC3 facilities and PC4 facilities. For other PC1 and PC2 facilities, only written confirmation that the **facility** complies with the conditions of certification is required.

### **Variation of certification conditions initiated by the Regulator**

- 3.23 The Act provides that the Regulator may vary the certification at any time by notice in writing given to the holder of a certification. The variation may entail imposing additional conditions or removing or varying conditions that were previously imposed by the Regulator.
- 3.24 Before the Regulator can unilaterally vary a certification, the Regulator must give written notice of the proposed variation to the holder of the certification. The notice may request relevant information from the holder of the certification and may invite a written submission from the holder of the certification. If a written submission is invited the Regulator's notice must specify a time period within which the holder of the certification may make the submission. The Regulator must consider any written submissions made.
- 3.25 The requirement that the Regulator provide prior notice of the variation to the holder of the certification may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the **environment**.

### **Suspension or cancellation of certification**

- 3.26 A certification can be either suspended or cancelled. Both can be at the instigation of the certification holder or the Regulator. When a certification holder requests the cancellation of a certification, the OGTR refers to the certification as being "surrendered".
- 3.27 Suspension does not override the expiry date on the certification instrument. If a certification is due to expire while under suspension an application can be made, by letter or

e-mail, to extend the certification while under suspension. However, any future lifting of the suspension may be conditional on the **facility** complying with any new requirements if the certification guidelines have been updated after the certification was suspended. Any certification holders in this position would need to contact the OGTR to discuss their situation.

- 3.28 The Act provides that the Regulator may, by notice in writing, suspend or cancel the certification of a **facility** if the Regulator believes on reasonable grounds that a condition of the certification has been breached.
- 3.29 When the Regulator instigates the suspension or cancellation of a certification, he/she must give written notice of the proposed suspension or cancellation to the holder of the certification.
- 3.30 The notice may request relevant information from the holder of the certification and may invite a written submission from the holder of the certification, within a designated timeframe. The Regulator must consider any written submissions.
- 3.31 The requirement for the Regulator to provide prior notice of the suspension or cancellation may be waived where the Regulator considers that the action is necessary to avoid an imminent risk of death, serious illness, serious injury or serious damage to the **environment**.
- 3.32 After the cancellation/surrender of a certification, no **NLRDs** or **DNIRs** can be conducted in the **facility**. Any stickers issued by the Regulator must be removed after cancellation/surrender.
- 3.33 In the case of the suspension of a certification, **NLRDs** and **DNIRs** may only resume in the **facility** after the Regulator has lifted the suspension. While the certification is suspended, any stickers or labels issued by the Regulator must be either covered or removed.

### **Review of the Regulator's decision**

- 3.34 Decisions by the Regulator to: refuse to certify a **facility**; specify a condition of a certification; vary a certification; or suspend or cancel a certification, are “reviewable decisions” under the Act.
- 3.35 If the original decision was not made by the Regulator in person, but by a delegate of the Regulator, an applicant may apply in writing to the Regulator for an internal review of the decision. An application for internal review must be made within 30 days after the day on which the decision first came to the notice of the applicant, or within such period (if any) as the Regulator, either before or after the end of that period, allows.
- 3.36 For decisions made by the Regulator personally, including decisions made on internal reviews, applicants may make an application to the Administrative Appeals Tribunal.

## **PART 4 – OTHER INFORMATION**

### **US National Institutes of Health Grants**

- 4.1 Several Australian organisations are conducting research funded by the US National Institutes of Health (NIH). The NIH requires all grant recipients conducting recombinant DNA research within the United States or its territories to comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).
- 4.2 For research in countries outside the US and its territories, section I-C-1-b-(3) of the NIH Guidelines April 2002 states:
- 4.3 “If the host country has established rules for the conduct of recombinant DNA research, then the research must be in compliance with those rules. If the host country does not have such rules, the proposed research must be reviewed and approved by an NIH-approved Institutional Biosafety Committee or equivalent review body and accepted in writing by an appropriate national governmental authority of the host country. The safety practices that are employed abroad must be reasonably consistent with the NIH Guidelines.”
- 4.4 Australia has legislation that establishes rules for the conduct of gene technology research and Australian recipients of NIH grants who comply with the Australian legislation meet the NIH requirements under section I-C-1-b-(3) of the NIH Guidelines April 2002.