



# **Guidelines for Accreditation of Organisations**

## **Version 2.1– Effective 1 July 2007**

The guidelines (Part A) contain the requirements for Accreditation of Organisations issued pursuant to section 98 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding state law.

Once an organisation is accredited, the accreditation instrument imposes conditions on the organisation pursuant to section 94 of the Act or, as applicable, corresponding state law. The conditions of accreditation (Part B), detail the usual conditions that will apply to an accredited organisation. Individual accreditation conditions may differ from these in some respect but generally an applicant can expect that their conditions will closely follow those published here. Once issued, the conditions may be varied by the Gene Technology Regulator as necessary and appropriate.

These Guidelines should be read in conjunction with the *Explanatory Information on Guidelines for Accreditation of Organisations* document, which contains details about the process of accreditation. This document can be downloaded from the OGTR website <[www.ogtr.gov.au](http://www.ogtr.gov.au)>.

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## Definitions and acronyms

Unless defined otherwise in these requirements, words and phrases used in the requirements have the same meaning as in 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).

**accredited organisation** An organisation accredited by the Gene Technology Regulator under Section 92 of the Act.

**dealing 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).

**instrument of accreditation** A current written instrument issued by **the Regulator** accrediting an organisation pursuant to Section 92 (1) of the Act.

**IBC** Institutional Biosafety Committee.

**the Regulator** The Gene Technology Regulator.

# Requirements for Accreditation

## Accreditation of Organisations Version 2.1 – Effective 1 July 2007

REQUIREMENTS THAT MUST BE MET IN ORDER FOR AN ORGANISATION TO BE ACCREDITED BY THE GENE TECHNOLOGY REGULATOR (THE REGULATOR).

Section 98 of the *Gene Technology Act 2000*

These are the requirements for the accreditation of an organisation issued under section 98 of the Act and, as applicable, corresponding State legislation. These requirements apply to applications for accreditation of organisations received on or after the day on which these guidelines take effect.

To be granted accreditation, an organisation must meet each of the requirements for accreditation of an organisation, unless the organisation receives a written exemption from meeting a particular requirement from **the Regulator**. (Note that it will not be possible to grant exemptions from requirements imposed by the Act.)

Because the application form covers all the requirements for accreditation of an organisation, if the form is completed correctly, all of the requirements will be addressed.

### Suitability Requirements

1. The applicant must satisfy **the Regulator** that the organisation is a suitable organisation to be accredited.
2. Without limiting the matters to which **the Regulator** may have regard in deciding whether the organisation is a suitable organisation to be accredited, **the Regulator** will have regard to:
  - (a) any conviction of the organisation within a period of ten years immediately before the making of the application, where the conviction is for an offence against a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment and punishable by a fine of \$5000 or more;
  - (b) any revocation, suspension or cancellation of a licence or permit (however described) held by the organisation under a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment; and
  - (c) the capacity of the applicant to comply with the conditions of accreditation that will generally be applied to an **accredited organisation**. These conditions are found in Part B of this document.

## Requirements in respect of Institutional Biosafety Committees (IBCs)

3. The applicant must satisfy **the Regulator** either that:
  - (a) it has established, and is capable of maintaining, its own **IBC**; or
  - (b) it has arrangements in place to use an **IBC** established by another **accredited organisation**.
  
- 3.1. If the organisation has established an **IBC**, the applicant must provide information to **the Regulator** to establish that:
  - (a) the membership of the **IBC** has the collective technical scientific expertise to review and assess all the matters that are likely be put to it by the organisation;
  - (b) the members of the **IBC** are appropriately indemnified; and
  - (c) at least one of the members of the **IBC** is independent.
  
- 3.2. If the organisation has arrangements in place to use an **IBC** established by another **accredited organisation**, the applicant must provide written confirmation to **the Regulator** that:
  - (a) the organisation has permission from the **accredited organisation** to use the **IBC**;
  - (b) the membership of the **IBC** has the collective technical scientific expertise to review and assess all the matters that are likely be put to it by the organisation;
  - (c) the members of the **IBC** are appropriately indemnified; and
  - (d) at least one of the members of the **IBC** is independent.

# Conditions of Accreditation

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Conditions are imposed on organisation by the Regulator at the time of accreditation pursuant to section 94 of the *Gene Technology Act 2000* (the Act) and, as applicable, corresponding State legislation. The condition clauses in this section are the ones that can be expected, in most cases, to be included in the accreditation instrument as the conditions of accreditation of an organisation.

### Suitability

1. The **accredited organisation** must at all times continue to be a suitable organisation to hold accreditation.

### Accredited organisation must use its IBC

2. Where any statute, rule, regulation or other legal obligation requires input from an **IBC** in the course of submitting information to **the Regulator**, the **accredited organisation** must obtain that input from an **IBC** nominated by this organisation for the purpose of accreditation.

### IBC must have technical scientific expertise

3. The **accredited organisation** must only use an **IBC** where the membership of the **IBC** possesses the collective technical and scientific expertise to assess and advise on the identification and management of risks associated with **dealings** with **GMOs** for which the **IBC** is requested or required to provide assessment and advice. An **IBC** will be compliant with this condition if it is necessary for it to rely on the advice of an expert (*i.e.* not a member of the **IBC**) to address specific, short-term skills deficit in the **IBC**.

### IBC must have an independent member

4. The **accredited organisation** must only use an **IBC** where the membership of the **IBC** includes a person who is independent from the accredited organisation.

### IBC members must be appropriately indemnified

5. The **accredited organisation** must only use an **IBC** where the members of the **IBC** are appropriately indemnified.

### Records must be kept

6. The **accredited organisation** must ensure that records of the following are kept:
  - (a) all current notifiable low risk **dealings** and licensed **dealings** conducted by the organisation;

- (b) minutes of meetings of the **IBC**; and
  - (c) inspections of certified facilities.
7. Records must be kept for at least 3 years from the time they are made.
8. Records must be made available for inspection by **the Regulator**, on **the Regulator's** request.

### **Conflicts of interest of IBC members must be declared**

9. The **accredited organisation** must only use an **IBC** where the **IBC** has arrangements in place to deal with conflicts of interest and these arrangements must include requirements that:
- (a) an **IBC** member who has a conflict of interest must declare the conflict of interest prior to the commencement of any meeting to consider that matter. If the **IBC** member does not have notice of the matter prior to the meeting, the member must declare the conflict of interest immediately upon becoming aware of it; and that
  - (b) minutes of **IBC** meetings contain records of all declared conflicts of interest and of any measures taken to address the conflict of interest.

### **Reports and notices must be prepared and submitted**

10. As soon as practicable after the end of each financial year, and before the following 30 September, the **accredited organisation** must complete and submit to **the Regulator** an annual report in the form required by **the Regulator**.
11. The **accredited organisation** must provide a notice in writing to **the Regulator** within 30 days, if the **accredited organisation**:
- (a) wishes to access or establish an **IBC** other than the **IBC(s)** identified in their application; or
  - (b) disbands or ceases to use an **IBC**; or
  - (c) changes the organisation's primary contact or contact details for the organisation's primary contact; or
  - (c) changes its **IBC** primary contact or the contact details of its **IBC** primary contact (where the **IBC** is the **accredited organisation's** own **IBC**); or
  - (d) changes its name or ownership. The notice must include details of any changes to the information provided as a part of the organisation's accreditation application; or
  - (e) is convicted of an offence against a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment and punishable by a fine of \$5000 or more; or
  - (f) has had a licence or permit (however described), held by the organisation under a law of the Commonwealth, a State or a foreign country relating to the health and safety of people or the environment, revoked, suspended or cancelled.