Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Guidelines for Accreditation of Organisations

Version 2.2– Effective 31 August 2012

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 legislation.

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 legislation. 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.

Contents

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.

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.

Part A

Requirements for Accreditation

Accreditation of Organisations
Version 2.2 – Effective 31 August 2012

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 that either:

   (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.

4. If the organisation has established an IBC, the applicant must provide information to the Regulator to establish that:

   (c) the membership of the IBC has the collective technical and scientific expertise to review and assess all the matters that are likely be put to it by the organisation;

   (d) the members of the IBC are appropriately indemnified; and

   (e) at least one of the members of the IBC is independent.

5. 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:

   (f) the organisation has permission from the accredited organisation to use the IBC;

   (g) the membership of the IBC has the collective technical and scientific expertise to review and assess all the matters that are likely be put to it by the organisation;

   (h) the members of the IBC are appropriately indemnified; and

   (i) at least one of the members of the IBC is independent.

Part B

Conditions of Accreditation

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Conditions are imposed on an 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 the accredited organisation for the purpose of accreditation.

3. The accredited organisation must continue to have access to at least one of their own, or another organisation's, IBC.

IBC must have technical and scientific expertise

4. 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

5. 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

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

Records must be kept

7. The accredited organisation must ensure that the following are kept:

   (a) records of meetings of the IBC for a minimum of 3 years from the date of each meeting.

   (b) records of inspections of facilities for a minimum of 3 years from the date of each inspection.

   (c) records of assessment of notifiable low risk dealings for a minimum of 8 years after the date of assessment by the IBC.

8. Records must be made available for inspection by the Regulator upon 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 conflicts 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;

   (b) disbands or ceases to use an IBC;

   (c) changes its primary contact or the contact details for the primary contact;

   (d) changes its IBC contact or the contact details for its IBC contact (where the IBC is the accredited organisation's own IBC);

   (e) changes its CEO (or equivalent) or the contact details for the CEO (or equivalent);

   (f) changes its IBC chair or the contact details for its IBC chair (where the IBC is the accredited organisation's own IBC);

   (g) changes its name or ownership;

   (h) 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

(i) 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.