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

Explanatory Information on the Guidelines for Accreditation of Organisations

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Version 1.2

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EXPLANATORY INFORMATION

Copies of the *Gene Technology Act 2000*, the *Gene Technology (Consequential Amendments) Act 2000*, the *Gene Technology (Licence Charges) Act 2000* and the *Gene Technology Regulations 2001* may be downloaded from the following websites: http://www.ogtr.gov.au or http://www.comlaw.gov.au

IMPORTANT NOTE

These explanatory notes may be updated from time to time. Users should therefore assure themselves that they have access to the most recent version.

Definitions

Unless defined otherwise in this Explanatory Information document, words and phrases used in this document have the same meaning as in the *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).

accredited organisation	An organisation accredited by the Gene Technology Regulator under s92 of the Act.
Accreditation guidelines	The Regulator's *Guidelines for the Accreditation of Organisations*
the Act	The Commonwealth *Gene Technology Act 2000.*
corresponding State law	A law that the Minister has declared to be a corresponding state legislation.
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).
DIR	Dealing Involving Intentional Release.
DNIR	Dealing Not Involving Intentional Release.
GMO	Genetically Modified Organism.
GT	Gene Technology.
Guidelines	Guidelines for the Accreditation of Organisations.
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.
NLRD	Notifiable Low Risk Dealing.
OGTR	Office of the Gene Technology Regulator.
the Regulations	The Commonwealth *Gene Technology Regulations 2001*.
the Regulator	The Gene Technology Regulator**.**
relevant conviction	means a conviction for an offence against a law of the Commonwealth, a State or a foreign country , being a law relating to the health and safety of people or the environment, if: (a) the offence was committed within the period of 10 years immediately before the making of the application for the licence; and (b) the offence was punishable by a fine of $5000 or more, or by a term of imprisonment of one year or more.

PART 1 - INTRODUCTION

1.1 The *Gene Technology Act 2000* (‘**the Act**’), the *Gene Technology Regulations 2001* (‘the Regulations’), together with corresponding state legislation, provide the legislative foundation for Australia’s nationally consistent scheme for the regulation of gene technology.

1.2 The objectives of the national 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 **dealing**s with genetically modified organisms (**GMO**s).

1.3 The national laws prohibit **dealing**s with **GMO**s, other than a limited range of permissible, authorised **dealing**s. They establish a statutory officer, the Gene Technology Regulator (‘**the Regulator**’), who is responsible for administering these laws. Part of that role includes responsibility for promoting compliance with the laws, and prosecuting non-compliance.

1.4 By encouraging good compliance practices by regulated organisations, particularly through the promotion and implementation of best practice techniques, the possibility of adverse environmental or human health outcomes associated with gene technology is reduced.

1.5 **The Regulator** strongly encourages all organisations conducting **dealing**s with **GMO**s to obtain accreditation.

Institutional Biosafety Committees (IBCs)

1.6 Fundamentally, best practice is achieved when organisations regularly and routinely seek, and obtain assistance from, a properly constituted, resourced and maintained Institutional Biosafety Committee (**IBC**), whose members are able to provide professional and unfettered advice on risks related to the gene technology work of the organisation.

1.7 **IBC**s assist organisations by advising on the identification and management of the risks associated with **dealing**s with **GMO**s undertaken by the organisation, including the containment of **GMO**s and providing an interface with the **OGTR**.

1.8 Either having an **IBC**, or having access to one, is a pre-requisite to an organisation obtaining accreditation.

1.9 **IBC**s are required to be consulted and used by organisations in certain situations (essentially, depending on the nature of the work proposed to be undertaken by organisations), regardless of whether an organisation is accredited. For example, the notification of a low risk **dealing** requires that the **dealing** has been reviewed by an **IBC**, even if the **dealing** is undertaken by an organisation which is not accredited.

1.10 **The Regulator** only recognises **IBC**s established by **accredited organisation**s.

1.11 **IBC**s therefore play an integral role in assisting compliance with Australia’s national scheme laws. They are an important quality assurance system for regulated organisations.

1.12 It should be noted, however, that the role and responsibilities of **IBC**s and accreditation are limited in two important respects.

1.13 Firstly, **IBC**s are not intended to be responsible for the conduct of the organisations that they assist. Ultimately, **the Regulator** encourages organisations to make representations to **the Regulator** on their own behalf. **IBC**s are intended to provide relevant experience and a useful check and balance in the performance of **dealing**s with **GMO**s without attracting liability for damages, in the course of providing that assistance.

1.14 Secondly, accreditation does not automatically allow an organisation to undertake **dealing**s with **GMO**s. If an **accredited organisation** wishes to undertake work with **GMO**s it must still conduct proper inquiries to determine what type of approval is needed from **the Regulator**. More information about approvals processes can be obtained from the **OGTR** website: http://www.ogtr.gov.au

1.15 For example, if the work requires a licence from **the Regulator**, the applicant will be required to prepare a proposal in accordance with **the Regulator**'s information requirements. The application must be submitted to the **accredited organisation**'s **IBC**. The **IBC** must attach supporting information to the application, including its assessment of the application. Licensed **dealing**s with a **GMO** may only proceed if and when **the Regulator** issues the licence. The activities must then be undertaken in accordance with any conditions that **the Regulator** considers necessary, based on a case by case assessment.

1.16 Information about the application process and the technical and procedural requirements that must be addressed in an application, together with helpful hints to assist applicants to prepare their applications, is set out in Part 2 of this explanatory document.

What happens when an organisation becomes accredited?

1.17 Upon accreditation, **the Regulator** issues the organisation with an **instrument of accreditation**. The instrument denotes that the organisation has met the requirements for accreditation.

1.18 The instrument will set out:

- the name of the **accredited organisation**; and
- any conditions of the accreditation.

1.19 Generally, a range of conditions will be imposed on the organisation at the time of accreditation. The organisation must comply with the conditions, on an ongoing basis, in order to maintain the accreditation. The conditions ensure that the standards of review and compliance initially attained by the organisation in the course of gaining accreditation are maintained by the organisation on an ongoing basis.

1.20 More information about conditions of accreditation and how organisations can maintain their accreditation is set out in Part 3 of this explanatory document.

Additional Information

1.21 To assist potential applicants to obtain and retain accreditation, a series of commonly asked questions have been collated and answered in Part 4 of this explanatory document.

PART 2 – HOW TO GET ACCREDITED

Introduction – the process and form

2.1 An organisation can apply for accreditation by making written application to **the Regulator**. Application forms can be obtained from the Office of the Gene Technology Regulator or can be downloaded from the website: http://www.ogtr.gov.au

2.2 Applications must address a number of required technical and procedural matters. These matters are set out in **the Regulator**'s *Guidelines for the Accreditation of Organisations* (the **Accreditation guidelines**) and in the application form. Copies of the **Accreditation guidelines** can be downloaded from the **OGTR** website: http://www.ogtr.gov.au.

2.3 **The Regulator** considers the level of compliance with the technical and procedural requirements outlined in the **Accreditation guidelines** in determining whether to accredit an organisation.

2.4 **The Regulator** must decide whether to grant accreditation or not within 90 working days. If **the Regulator** requests further information in the course of consideration of the application, the 90 day time limit is suspended while **the Regulator** is waiting for information to be provided.

2.5 The application form requests information about the suitability of organisations to hold accreditation. It also makes provision for applications to be made in respect of organisations establishing at least one **IBC** of their own or arranging access to another organisation's **IBC**.

2.6 Because the accreditation application form covers all the matters required to be addressed, if the form is completed correctly, you will address all the relevant matters.

Organisations must be suitable to be accredited

2.7 Suitability to hold accreditation is a mandatory, threshold test that all **accredited organisation**s must satisfy. An organisation will not be accredited by **the Regulator** unless **the Regulator** is satisfied that the organisation is a suitable organisation.

2.8 In general terms, a suitable organisation is an organisation that is considered to be reasonably capable of conducting **dealing**s with **GMO**s safely. Another way of describing a suitable organisation might be to describe them as 'fit and proper' to conduct **dealing**s with **GMO**s.

2.9 Concepts of honesty, knowledge and ability are connoted by the expression 'suitable'.

2.10 Suitability is a broad assessment and **the Regulator** may have regard to any relevant information.

2.11 The range of matters to which **the Regulator** may have regard may extend beyond the organisation itself. For example, in considering the suitability of a wholly owned subsidiary company, **the Regulator** might, depending on the circumstances, investigate the reputation of the parent company and the closeness of the relationship between the organisation and its parent.

2.12 If an applicant previously had a **GMO** licence suspended or revoked by **the Regulator**, this would be relevant to **the Regulator**'s assessment of whether the person is a suitable person. An organisation's conduct in connection with other regulation might also be relevant.

2.13 If an organisation has **relevant convictions**, those convictions must be set out in the application form.

2.14 A **relevant conviction** may prevent an organisation from obtaining accreditation.

2.15 An organisation must also list 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.

2.16 An organisation must include information about the revocation, suspension or cancellation of licences and permits issued by:

a) The Therapeutic Goods Administration (http://www.tga.gov.au);
b) The Australian Quarantine and Inspection Service (http://www.daff.gov.au/aqis):
c) Food Standards Australia New Zealand (www.foodstandards.gov.au):
d) National Industrial Chemical Notification and Assessment Scheme (http://www.nicnas.gov.au);
e) Australian Pesticides and Veterinary Medicines Authority http://www.apvma.gov.au); or
f) Department of the Environment, Water, Heritage and the Arts (http://www.environment.gov.au/about/business/permits.html).

2.17 Other Commonwealth, State and Territory permit and licensing regimes could also be relevant.

2.18 The revocation, suspension or cancellation of an instrument like those described above may prevent an organisation from obtaining accreditation.

Requirements in respect of IBCs – technical knowledge, independence and indemnification

2.19 Applicant organisations are required to establish at least one **IBC** of their own or have access to another organisation's **IBC**.

2.20 An applicant organisation is able to obtain accreditation if it can demonstrate, in respect of the **IBC**, that:

- 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;
- the members of the **IBC** are appropriately indemnified; and
- at least one of the members of the **IBC** is independent.

2.21 Depending on the range of activity it conducts and the expertise it requires, an organisation may choose to utilize more than one **IBC**. Applicants must address each of the criteria in the application form.

A. IBCs must have technical expertise to assess and review matters

2.22 In order to perform its functions satisfactorily, an **IBC** will ideally have, within its membership, a breadth of relevant expertise both to understand and analyse hazards and risks associated with the particular **dealing**s and to provide expert commentary on those risks including, where relevant, any containment measures for **GMO**s involved in the **dealing**s.

2.23 The scientific and technical skills that will be necessary to enable an **IBC** to satisfactorily perform its functions satisfactorily will vary, depending on the type of research being conducted.

2.24 For example, an **IBC** considering gene technology work on potentially pathogenic micro-organisms might reasonably include a microbiologist and a biological safety expert, and would need to have expertise in the physical containment of organisms and in the nature of the **dealing**s or research being conducted.

2.25 An **IBC** overseeing tests of crop performance of **GMO**s might have a membership that includes, among other expertise, molecular biology, entomology, plant pathology, agronomy and ecology.

2.26 **IBC**s that oversee contained facilities that are certified to physical containment level PC3 or PC4, or PC1 Large Scale facilities and PC2 Large Scale facilities, will not ordinarily meet the criterion for technical expertise unless the **IBC** has expertise in physical containment of organisms. This comprises:

- understanding the building structural requirements, equipment and procedural requirements;
- relevant training or experience in the design and testing of biological safety facilities and equipment;
- relevant training or experience with proper procedures for the safety of persons and the containment of organisms; and
- knowledge of the biology and life cycles of organisms being used within the facilities.

2.27 To address this criterion in the application form, applicants are advised to:

- take stock of the scientific, technical and other professional skills of the membership of the **IBC** and the kinds of matters likely to be put to the **IBC** by the organisation; and
- document how those skills and experience will enable the **IBC** to efficiently and effectively assess and review the information that is likely to be put before it by the organisation.

2.28 It will be a condition of accreditation (and therefore an ongoing requirement) that an **accredited organisation** only use an **IBC** whose membership contains the requisite expertise. To account for requests for assessment of unanticipated risks and advice on **dealing**s with **GMO**s, reliance on the advice of an expert (not a member of the **IBC**) to address specific, short-term skills deficit in the **IBC** will be recognised by **the Regulator** as compliance with that condition of accreditation.

B. Someone on the IBC must be independent

Why is there a requirement for an independent member?

2.29 The intention in requiring an independent member is to include someone who can exercise unfettered and independent judgement in relation to their participation in the **IBC**.

How to address the criterion

2.30 To address this criterion, an applicant must make a statement in the application form that at least one member of the **IBC** has no ongoing, substantive association (including personal, pecuniary or research interests) with matters likely to be considered by the **IBC**.

Employees are discouraged from being denoted as independent members of **IBC**s

2.31 While it is not a requirement, **the Regulator** encourages members who satisfy the independence criterion to be free of any business or other relationship with the organisation that could materially interfere with the exercise of unfettered and independent judgement in contributing to decisions made by the **IBC**, including a relationship of employment.

C. IBC members must have appropriate indemnification

How to address the criterion

2.32 To address this criterion, an applicant must make a statement in the application form that all **IBC** members consider they are appropriately indemnified.

2.33 The statement can be made by the organisation itself, in terms as simple as 'the indemnity arrangements in place in respect of all **IBC** members, as regards the organisation, are satisfactory to them', or even 'All **IBC** members are appropriately indemnified'.

2.34 Alternatively, if the organisation prefers, it can provide written statements from each **IBC** member that the indemnity arrangements in place, as between the **IBC** member and the organisation, are satisfactory.

2.35 An indemnification arrangement is appropriate if it is in place and satisfactory to the **IBC** member covered by it. That is, indemnity arrangements are satisfactory if the **IBC** members consider that they are protected from legal liability for damages, as a result of their performing functions as an **IBC** member.

2.36 **IBC** members and organisations are encouraged to obtain their own separate legal advice in coming to arrangements between them.

Why are there indemnity requirements and why aren't they standardised?

2.37 **IBC**s provide advice and assistance to organisations on matters that were historically not regulated, but are now regulated under **the Act**.

2.38 To address this, indemnity requirements benefiting **IBC** members are a requirement in the **Guidelines**. At its simplest, the requirement for indemnity arrangements provides comfort to **IBC** members so that they continue to provide a valuable service to organisations.

2.39 Implementing prescribed, standard indemnity arrangements between **IBC** members and organisations has been considered on a number of occasions. However, because the indemnity requirement is included to provide comfort to **IBC** members via what is essentially a private arrangement between an **IBC** member and an organisation, the **Guidelines** do not prescribe particular indemnity arrangements. Put simply, if an **IBC** member is satisfied, the objective of the indemnity requirement is achieved.

2.40 Indemnities can therefore take many different forms, depending on a range of matters, including the nature and extent of the activities they are made in contemplation of, and people's attitudes towards them. These arrangements provide flexibility to **IBC** members and organisations to settle arrangements that are satisfactory to them by not prescribing any particular indemnity arrangement (or a minimum requirement).

Requirements for use of other organisations' IBCs

2.41 For a variety of reasons, some organisations are not able to establish their own **IBC**s. For example many small institutions are not able to fund **IBC**s and many collaborative research arrangements exist where there is limited or no access to internal **IBC**s. It is still possible for these organisations to become accredited.

2.42 Organisations that have established arrangements to use an **IBC** belonging to another organisation can seek accreditation from **the Regulator**.

2.43 An applicant is able to obtain accreditation if they can demonstrate, in respect of the **IBC** of the other organisation, that:

- the other organisation has consented, in writing (on page 20 of the application form), to its **IBC** being accessed and used by the organisation seeking accreditation;
- the organisation that maintains the **IBC** has declared that:
  - the members of its **IBC** are appropriately indemnified, as regards the organisation seeking accreditation; and
  - the membership of the **IBC** includes at least one independent member.
  - 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 seeking accreditation.

2.44 Applicants must address each of the criteria in the application form.

2.45 In all other respects, the information requirements are equivalent to those for applications in respect of **IBC**s created by the organisation. Applicants should refer back to earlier information in this explanatory document about skills and experience and indemnification requirements.

Helpful Hints – Applications for Accreditation

Answer requests for information promptly

2.46 If **the Regulator** requests further information from you in the course of considering an application, please provide the information promptly. Failure to do so may slow the consideration of your application, or even result in its refusal.

2.47 Generally, **the Regulator** must make a decision on an application for accreditation within 90 working days.

2.48 But if **the Regulator** requests further information from you, the 90 day time frame will be suspended until the information is provided.

2.49 If **the Regulator** stipulates a timeframe within which any requested information must be provided, and the information is not provided in time and without reasonable excuse, **the Regulator** may refuse the application.

Applications that don't meet all the requirements

2.50 Organisations should not be discouraged from highlighting aspects of applications that are not fully compliant with the **Guidelines**, particularly if they also have proposals for how full compliance, or equivalent compliance, might be achieved by the organisation in a reasonable period following accreditation. **The Regulator** is empowered to grant accreditation subject to conditions. In appropriate circumstances, **the Regulator** may consider imposing conditions at the time of accreditation allowing an organisation to work towards reaching full compliance.

What if I don't agree with a decision?

2.51 Decisions by **the Regulator** to refuse an application for accreditation, to impose conditions, or to vary, suspend or cancel accreditation are "reviewable decisions" under **the Act**. This means that an applicant may seek review of the decision by the Administrative Appeals Tribunal (AAT).

2.52 The AAT undertakes merit reviews of administrative decisions. The AAT may:

- stay the operation or implementation of a decision until the AAT hearing;
- affirm the decision made by the decision maker;
- vary the decision;
- set aside the decision;
- substitute its own decision; or
- remit the matter to the original decision maker with directions or recommendations for re-making the decision.

PART 3 – HOW TO STAY ACCREDITED

Introduction

3.1 Upon accreditation, **the Regulator** issues an **instrument of accreditation** to the organisation. The instrument denotes that the organisation has met the requirements for accreditation.

3.2 The instrument sets out:
- the name of the **accredited organisation**; and
- any conditions of accreditation.

3.3 A range of conditions will ordinarily be imposed on an organisation at the time of accreditation. Organisations must comply with any conditions imposed (on an ongoing basis), in order to maintain the accreditation.

3.4 Conditions imposed at the time of accreditation are designed to ensure that compliance with the standards of review is maintained by the organisation on an ongoing basis. They also establish minimum standards for the organisation and the relevant **IBC** on a range of matters affecting the **IBC** and its use by the organisation.

3.5 As a result, **accredited organisation**s will be required to:
- Develop and implement processes and procedures to address conflicts of interest;
- Keep satisfactory records; and
- Prepare and submit annual reports and other notices to **the Regulator**.

3.6 Depending on the circumstances, **the Regulator** may also impose other conditions at the time of accreditation.

3.7 The usual conditions are outlined in the **Accreditation guidelines**; some of the usual conditions are also explained in more detail below.

Usual conditions of accreditation

A. Continuing requirements to address conflicts of interest

3.8 There may be occasions where a proposal submitted by organisations arises from the recommendations of an **IBC** where one or more of the members of the **IBC** have a close involvement in the matter being considered. This may give rise to a conflict of interest, or a perception of a conflict of interest.

3.9 For the purposes of the **Guidelines**, a 'conflict of interest' in a matter includes:
- a direct financial interest;
- an indirect interest, for example a financial benefit accruing to a close relative or partner of the member;
- a non-financial interest, for example a person may have an interest in a matter as a result of an affiliation or membership of an interest group or organisation;
- an interest that could be perceived to represent a possible conflict of interest; and
- combinations of the above interests.

3.10 It is **the Regulator**'s policy to ordinarily impose conditions at the time of accreditation requiring **accredited organisation**s to have effective mechanisms in place to address conflicts of interest on the part of **IBC** members.

3.11 In general terms, conditions along these lines imposed at the time of accreditation will give effect to this policy by:

- requiring **IBC** members to declare conflicts of interest, whether direct or indirect, pecuniary or otherwise, perceived or real;
- requiring declared conflicts to be recorded in the minutes of **IBC** meetings along with any measures taken to address the conflict; and
- enabling **IBC**s to decide for themselves whether, in a particular instance, a conflict of interest is so significant that an **IBC** member be absented from further participation in a matter before the **IBC**.

3.12 The **Accreditation guidelines** contain draft conditions of accreditation dealing with conflicts of interest. The draft clauses are likely to form the basis of any conditions actually imposed.

B. Continuing requirements to keep records and make reports to the Regulator

3.13 Good records, good records practices and good reporting practices are all important tools in the proper management of **dealing**s with **GMO**s. For example, in the event of a breach of containment, proper records and reporting may be essential to ensuring that the causes and impacts of the breach can be identified and redressed.

3.14 It is **the Regulator**'s policy to require **accredited organisation**s to maintain a minimum standard of good records keeping and reporting practice.

3.15 In general terms, conditions along these lines imposed at the time of accreditation will give effect to this policy by requiring:

- registers to be kept in respect of all notifiable low risk **dealing**s (NLRDs) and licensed **dealing**s (DIRs and DNIRs) conducted by the organisation;
- minutes of meetings of **IBC**s to be kept, for the minutes to be kept for a minimum of 3 years, for the minutes to record all conflicts of interest declared to the **IBC**;
- annual reports to be submitted to **the Regulator**;
- records of all inspections of certified facilities; and
- notice in writing to the Regulator within 30 days if the accredited organisation establishes or disbands an **IBC**, changes contact details for primary contacts of the organisation or its **IBC**, changes its name or ownership, is convicted of an offence relating to the health and safety of people or the environment or has a licence or permit revoked, suspended or cancelled.

3.16 All records must be available for inspection by **the Regulator** upon request.

3.17 As regards the detail of annual reports, it is **the Regulator**'s policy that accreditation conditions in respect of annual reports will require them to:

- report for the period 1 July to 30 June in the following year ('the reporting period');
- be submitted by 30 September each year; and
- list all **NLRD**s assessed by an IBC in the reporting period.

3.18 **The Regulator** publishes a form for annual reporting by **accredited organisation**s. In most cases, **accredited organisation**s can satisfy annual reporting conditions of accreditation by filling out the form correctly and submitting it on time.

3.19 **Accredited organisation**s should take special note that if they hold **GMO** licences, those licences may impose separate, additional annual and other reporting obligations on them.

Monitoring and varying accreditations

Monitoring and non-compliance with accreditation conditions

3.20 **Accredited organisation**s are monitored by **the Regulator**, to ensure that they are operating in accordance with any conditions of accreditation imposed on them. **The Regulator** also monitors, audits and inspects **dealing**s with **GMO**s, to ensure that any conditions particular to certain **dealing**s with **GMO**s are being observed.

3.21 The **OGTR** has programs for both routine (announced) and on-the-spot (unannounced) monitoring visits to **accredited organisation**s to assess compliance with their conditions of accreditation. During monitoring visits, monitoring officers may ask to look at records and standard operating procedures held and used by the organisation.

3.22 **Accredited organisation**s are encouraged to contact the **OGTR** if they find that they have not complied with their conditions of accreditation.

3.23 Where conditions of accreditation have not been met, **the Regulator** has recourse to the **OGTR**'s Monitoring and Compliance Unit protocols and the Compliance and Enforcement policy. Further information can be obtained from the **OGTR** website: http://www.ogtr.gov.au

Variation of accreditation

3.24 To allow accreditations to adjust to changing circumstances, instruments of accreditation are able to be varied. **The Regulator** may impose additional conditions, remove or vary conditions previously imposed, either on the initiative of **the Regulator** or in response to a request.

3.25 If you consider that variations to your conditions of accreditation are necessary or desirable, you are welcome to contact the **OGTR** to discuss how changes to your accreditation might be made.

3.26 If circumstance arise such that **the Regulator** considers a variation of your accreditation is desirable, **the Regulator** will consult you in connection with the proposed variation before any variation decision is made.

PART 4 –QUESTIONS AND ANSWERS

4.1 Who is authorised to complete an accreditation application form?

The accreditation application form can be completed by anyone authorised to act on behalf of the organisation to complete the form.

4.2 Who is authorised to sign the declaration of the organisation submitting the accreditation application?

The CEO (or equivalent) or a person with the authority to sign on behalf of the organisation, is authorised to sign the application form.

4.3 What is the role of the organisation's primary contact officer?

The organisation's primary contact officer is the first point of contact for all matters that the **OGTR** would like to discuss. This role will involve receiving written correspondence and telephone enquiries from the **OGTR**.

4.4 Who should be the primary contact of the IBC?

The **OGTR** does not dictate who should take on the role of primary contact for the **IBC**. The **IBC** is required to make its own decision regarding who is the most suitable person. The committee should be aware, however, that the **OGTR** will be contacting the primary contact for matters relating to the **IBC**, applications and notifications.

4.5 How long does an accreditation last?

Accreditations are issued without an expiry date; however **the Regulator** can choose to issue an accreditation with an expiry date. If an accreditation has an expiry date, the date will be set out in the **instrument of accreditation**.

4.6 Is there an application fee for accreditation?

There is no application fee at the time of issue of these explanatory notes.

4.7 How long does it take to assess an application?

Accreditations must be decided within 90 working days of the application being received by the Regulator, plus any time spent waiting for responses to requests for additional information from the applicant.

4.8 What are the functions of an IBC?

The function of an **IBC** is to provide assistance to an **accredited organisation** in relation to the gene technology **dealing**s that the organisation undertakes. Specifically this involves:

For Facilities

- inspecting or arranging inspections of PC1 large scale certified facilities, PC2 large scale certified facilities and of all PC3 and PC4 certified facilities.

For Licensed dealings

- confirming that for applications for licensed **dealing**s the information provided to **the Regulator** is complete;
- confirming that personnel are adequately trained to undertake the **dealing**; and
- evaluating the proposed project.

For NLRDs

- assessing the proposal for an **NLRD**;
- making a record of the dealing in a form approved by the Regulator;
- giving a copy of the record to the person or accredited organisation that requested the **IBC** assess the proposed dealing;
- giving a copy of the record to the project supervisor for the proposed dealing; and
- confirming that personnel are adequately trained to undertake the **dealing**.

4.9 Does the OGTR have specific terms of reference for IBCs?

Currently the **OGTR** does not have any specific model terms of reference for **IBC**s. In general an organisation setting out an **IBC**'s terms of reference could include the scope of its responsibilities, relationship to non-affiliated researchers, accountability and mechanisms of reporting.

The terms of reference could generally contain such information as:

- Composition of its membership
- Appointment of members
- Working procedures
- Conflict of interest procedures
- Financial affiliations
- Inspection of certified facilities
- Recording of decisions
- Monitoring of the organisation's research
- Complaints mechanisms
- Procedures for suspension or discontinuation of research
- Annual reporting requirements to **OGTR**
- Record keeping requirements

4.10 What is the role of the IBC Chair?

A member of the **IBC** should be appointed Chair of the **IBC**. The Chair of the **IBC** shall convene meetings of the **IBC** and is to provide leadership and direction to the conduct of the business of the **IBC**. Arrangements should be in place for another member to act as the Chair if the need arises.

4.11 What expertise must the IBC have?

IBCs must have the collective expertise to competently assess and advise on the identification and management of the risks associated with **dealing**s with **GMO**s undertaken by the organisation(s) and to advise on the containment of **GMO**s. The composition of individual **IBC**s will therefore depend on the **dealing**s with **GMO**s and the nature of the work being undertaken by the organisation(s).

4.12 Can an organisation utilise more than one IBC?

An organisation may choose to utilise more than one **IBC** because external **IBC**s may have more extensive experience in certain aspects of an organisation's **dealing**s. This expertise can be sought and utilised through any number of internal and external **IBC**s.

At the time of application, the organisation must notify the **OGTR** if additional **IBC**s are to be accessed, using the relevant part of the accreditation application form.

4.13 If an organisation wishes to access an additional IBC or cease to access an existing IBC, what action is required?

If an organisation wishes to add or remove an **IBC** to/from their accreditation, the **OGTR** requires notification of this change. The organisation should send formal correspondence to the **OGTR** requesting that the **IBC** is added or removed, as appropriate. Relevant pages of the accreditation application form should be completed and sent to the **OGTR** with a covering letter explaining the change. The **OGTR** will then undertake a variation of accreditation and post out the amended accreditation instrument when available.

4.14 How many meetings per year is the IBC expected to hold?

The **OGTR** does not prescribe internal operating procedures for **IBC**s. The committee should come to an agreement on how many meetings are needed to ensure that all **OGTR** requirements, in relation to **dealing**s with **GMO**s and inspections of certified facilities, are met.

4.15 What is the minimum number of members required to attend IBC meetings?

The committee can agree on how many members are required at a meeting to make a decision. These rules, however, must ensure that the purpose of the **IBC** to provide oversight of the organisation's activities in relation to **GMO**s and a robust scientific assessment of licence applications, are achieved. The **IBC** should have sufficient expertise at the meetings to assess the applications and ensure that all risks associated with **dealing**s are considered.

4.16 What constitutes a conflict of interest?

A 'conflict of interest' in a matter may include:

- a direct financial interest;
- any indirect interests, for example a financial benefit accruing to a close relative or partner of the member;
- a non-financial interest, for example a person may have an interest in a matter as a result of an affiliation or membership of an interest group or organisation;
- any interests that could be perceived to represent a possible conflict of interest; and
- combinations of the above interests.

IBC members must declare any such conflict of interest whether direct or indirect, pecuniary or otherwise, and perceived or real.

4.17 Do conflict-of-interest procedures need to be formal?

Procedures for conflict of interest need to be established and formalised in relevant documents. Organisations must have documents and procedures in place that define conflict of interest and require members of the **IBC** to declare any conflict of interest. Any conflict of interests must be recorded in the minutes of the relevant **IBC** meeting along with any measures taken to address the conflict of interest.

4.18 Why are IBCs required to have an independent member?

An independent member is required to include someone who can exercise unfettered and independent judgement in relation to the work of the **IBC**. This alternate perspective should facilitate a balanced consideration of proposals.

4.19 Where can I get a copy of the Gene Technology Act 2000?

A copy of the *Gene Technology Act 2000* can be downloaded from the following websites: http://www.comlaw.gov.au or http://ww.ogtr.gov.au

4.20 If an organisation decides to change its name, what action is required?

If an **accredited organisation** chooses to change its name the **OGTR** needs to be informed. This is because the organisation's records need to be updated and the accreditation instrument needs to be amended and reissued. The organisation should send correspondence to the **OGTR** via email or in a letter explaining the change and requesting a variation to their accreditation. The **OGTR** will then undertake a variation of accreditation and post out the amended accreditation instrument when available.