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

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 213

Licence Holder: Novotech (Australia) Pty Ltd

Clinical trial with a genetically modified human adenovirus for the treatment of melanoma

Issued: 11 June 2025

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding State and Territory legislation form a substantial part of a nationally consistent regulatory system controlling the development and use of genetically modified organisms.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the *Gene Technology Act 2000* and, as applicable, corresponding State law.

In assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment, the Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment.

Other agencies that also regulate genetically modified organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Water and the Environment. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in **Attachment A** of this licence.

Further information on licence DIR 213

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator (OGTR) website or by telephoning the Office on 1800 181 030.

CONDITIONS OF THIS LICENCE

Section 1 Interpretations and Definitions

1. In this licence:

   (a) unless defined otherwise in this licence, words and phrases used in this licence have the same meaning as they do in the Act and the Regulations;

   (b) words importing a gender include every other gender;

   (c) words in the singular number include the plural and words in the plural number include the singular;

   (d) expressions used to denote persons generally (such as "person", "party", "someone", "anyone", "no one", "one", "another" and "whoever"), include a body politic or corporate as well as an individual;

   (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

   (f) where a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;

   (g) specific conditions prevail over general conditions to the extent of any inconsistency.

2. In this licence:

   'Act' means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State law under which this licence is issued.

   'Analytical facility' means a laboratory in Australia accredited to undertake testing of human diagnostic Samples, such as a medical testing laboratory accredited by the National Pathology Accreditation Advisory Council (NPAAC).

   'Clinical trial site' means a medical facility in Australia such as a clinical trial facility and associated Pharmacy, which are notified in writing to the Regulator for the purposes of conducting this clinical trial.

   'Decontaminate' (or ***'Decontamination'***) means, as the case requires, kill the GMOs by one or more of the following methods:

   (a) chemical treatment;

   (b) autoclaving;

   (c) high-temperature incineration; or

   (d) a method approved in writing by the Regulator.

   Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

   'External service provider' means a person engaged by the licence holder solely in relation to transport, storage and/or disposal of the GMOs, and who is not undertaking any dealings with the GMOs that are not for those purposes.

   'GM' means genetically modified.

'*GMO'* means the genetically modified organisms that are the subject of the dealings authorised by this licence.

'NLRD' is a Notifiable low risk dealing. Dealings conducted as an NLRD must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Regulations.

'OGTR' means the Office of the Gene Technology Regulator.

'Personal information' has the same meaning as in the *Privacy Act 1988*. Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not; and

(b) whether the information or opinion is recorded in a material form or not.

'Pharmacy' means a location within the Clinical trial site, where authorised staff store, prepare, and dispense medications in a medical environment.

'Regulations' means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

'Regulator' means the Gene Technology Regulator.

'Sample' means any biological material collected from a treated trial participant for analysis as part of the trial

'Storage facility' means a third-party facility offering logistical services and distribution of clinical supplies.

Section 2 General conditions and obligations

Holder of licence

3. The licence holder is Novotech (Australia) Pty Ltd.

Remaining an Accredited Organisation

4. The licence holder must, at all times, remain an accredited organisation.

Validity of licence

5. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension, or after the licence has been cancelled or surrendered.

Note: Although this licence has no expiry date, the duration of preparation and administration of the GMOs is restricted in accordance with Condition 23.

Persons covered by this licence

6. The persons covered by this licence are:

   (a) the licence holder, and any employees, agents or External service providers engaged by the licence holder; and

   (b) the project supervisor(s); and

   (c) other persons who are, or have been, engaged or otherwise authorised by the licence holder or the project supervisor to conduct any of the dealings authorised by this licence.

7. To the extent that any activity by a trial participant may be considered to be a dealing with the GMO as described in **Attachment A** for purposes of the Act, that dealing is authorised by this licence.

8. The licence holder must keep a record of all persons covered by this licence, and must keep a record of the contact details of the project supervisor(s) for the licence.

Note: Where External service providers are used, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.

9. The licence holder must provide information related to the persons covered by the licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Description of GMOs covered

10. The licence authorises specified dealings in respect of the GMOs identified and described in **Attachment A**.

Dealings authorised by this licence

11. The licence holder and persons covered by this licence may conduct the following dealings with the GMOs:

    (a) import the GMO;

    (b) conduct the following experiments with the GMOs:

        i) prepare the GMO for administration to trial participants;

        ii) administer the GMO to trial participants by intra-tumoural administration;

        iii) collect Samples from trial participants;

        iv) analyse the Samples described in 11(b)iii);

    (c) transport the GMOs;

    (d) dispose of the GMOs;

    and may possess, supply, use or store the GMO for the purposes of, or in the course of, any of these dealings.

12. Supply of the GMOs for the purposes of dealings by a person or organisation not covered by this licence is only authorised by this licence if the Regulator provides prior written approval to the licence holder.

Note: For approval to be granted, the receiving person or organisation must have an appropriate authorisation to conduct dealings with the GMOs. This is likely to be a NLRD or a licence issued by the Regulator.

Conditions imposed by the Act

Note: The Act mandates the following 3 conditions.

Informing people of licence conditions (section 63)

13. The licence holder must inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:

    (a) the particular condition, including any variations of it; and

    (b) the cancellation or suspension of the licence; and

(c) the surrender of the licence.

Note: No particular conditions of this licence apply to trial participants; therefore, Condition 13 does not apply to trial participants.

Monitoring and audits (section 64)

14. If a person is authorised by this licence to deal with the GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Additional information to be given to the Regulator (section 65)

15. The licence holder must immediately inform the Regulator, if they become aware of:

    (a) additional information about any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

    (b) any contraventions of the licence by a person covered by the licence; or

    (c) any unintended effects of the dealings authorised by the licence.

Note 1: For the purposes of this condition:

(a) The licence holder is taken to have become aware of additional information if they were reckless as to whether such information existed; and

(b) The licence holder is taken to have become aware of contraventions, or unintended effects, if they were reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note 2: Contraventions of the licence may occur through the action or inaction of a person.

Note 3: Additional information includes any changes at a Clinical trial site, which might increase the likelihood of unintentional exposure of people or release of the GMO into the environment.

Note 4: An example of informing immediately is contact made at the time of the incident via the OGTR free call phone number 1800 181 030 or email to OGTR.M&C@health.gov.au.

Informing the Regulator of any material changes of circumstance

16. The licence holder must immediately, by notice in writing, inform the Regulator of:

    (a) any relevant conviction of the licence holder occurring after the commencement of this licence;

    (b) any revocation or suspension after the commencement of this licence, of a licence or permit held by the licence holder under 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;

    (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it.

17. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator, and must provide the information within a time period stipulated by the Regulator.

Further conditions with respect to informing persons covered by the licence

18. If a particular condition, including any variation of it, applies to an External service provider covered by this licence, the licence holder must not permit that person to conduct any dealings unless the person has been informed of the condition, including any variation of it.

Note: Information required under Condition 18 may be provided to External service providers who are engaged solely for storage and transport of the GMO through labelling of the outermost container of the GMOs in accordance with Condition 36(a).

19. If a particular condition, including any variation of it, applies to a person with respect to any dealing, other than to an External service provider, the licence holder must not permit a person covered by this licence to conduct that dealing unless:

    (a) the licence holder has obtained from the person a signed and dated statement that the person:

        i) has been informed by the licence holder of the condition and, when applicable, its variation; and

        ii) has understood and agreed to be bound by the condition, or its variation; and

        iii) has been trained in accordance with sub-condition 19(b) below; and

    (b) the licence holder has trained that person in a manner which enables them to conduct the dealings in accordance with the conditions of this licence.

20. The licence holder must notify all persons covered by the licence, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

21. The licence holder must ensure that a copy of the licence is readily available to all persons covered by the licence, other than External service providers, who are conducting dealings with the GMO.

Note: The licence may be made available electronically.

Section 3 Limits and control measures

Limits on clinical trials conducted under this licence

22. The GMO may be administered to a maximum of 30 trial participants.

23. The preparation and administration of the GMO must be completed within 3 years from the date of issuing of the licence.

Preparation and administration of the GMOs

24. Administration of the GMO to trial participants must not commence prior to approval by a Human Research Ethics Committee.

25. The following activities must occur within a Clinical trial site:

    (a) preparation of the GMO for administration to trial participants; and

    (b) administration of the GMO to trial participants.

Note: Before any of these activities take place, the details of each Clinical trial site must have been notified to the Regulator in accordance with Condition 42(a).

Conditions relating to trial participants

26. The licence holder must notify each trial participant, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.

27. The licence holder must ensure that exclusion criteria used in selecting trial participants include (though are not limited to) the following persons:

    (a) pregnant and breastfeeding women;

    (b) any people suffering from an active infection or any immunosuppressive disorder;

    (c) those having received a prior treatment with an oncolytic virus within two months prior to screening;

    (d) those intending to become pregnant during the trial or during the first 60 days following each treatment with the GMO.

28. Before inoculating any trial participant with the GMOs, the licence holder must obtain written agreement from the trial participant that they would:

    (a) use barrier contraception for the duration of the trial and for 60 days after each treatment with the GMO; and

    (b) not donate blood, sperm, ova, tissues or organs while participating in the trial and for 60 days after their last treatment with the GMO.

    Note: Condition 28(a) is intended to minimise physical contact or exchange of bodily fluids during sexual activity in addition to preventing conception.

Conditions related to the conduct of the dealings

29. Conditions that apply to dealings with GMOs do not apply to Samples collected from trial participants, or other materials or waste, that are reasonably expected not to contain the GMO. The licence holder must provide to the Regulator upon request, a written justification for this expectation.

30. The licence holder must ensure that dealings are only conducted in a manner which:

    (a) does not compromise the health and safety of people; and

    (b) minimises the exposure of persons conducting the dealings to the GMO, other than intended exposure of trial participants.

    Note: The licence holder may achieve this by only engaging or otherwise authorising persons to conduct dealings who are required to adhere to appropriate standards and guidelines. For example, standards developed by the National Pathology Accreditation Advisory Council for pathology practices, the Australian Guidelines for the Prevention and Control of Infection in Healthcare, Guidelines for Good Clinical Practice and the National Safety and Quality Health Service (NSQHS) Standards.

31. The licence holder must ensure that procedures are in place to account for the GMO from import to destruction/export, and records must be made available to the Regulator on request.

Work practices at Clinical trial sites

32. For the purposes of Condition 30, work practices and behaviours within a Clinical trial site must include, but are not limited to, the following:

    (a) Persons preparing and administering the GMO must:

i) be suitably qualified and trained in conducting dealings with the GMO;

ii) be informed of the risks associated with the GMO, particularly risks for persons who are immunosuppressed or pregnant;

iii) have provided a signed statement to that effect in accordance with condition 19;

(b) preparation of the GMO must be conducted in a Class II biosafety cabinet (Class II BSC), or alternative containment equipment approved in writing by the Regulator;

(c) persons preparing the GMO must wear personal protective equipment (PPE), including gowns, gloves, and eye protection.

(d) persons administering the GMO must wear PPE including gowns, gloves, eye protection and an N95 or equivalent facemask;

(e) all work surfaces must be Decontaminated after they have been used for conducting dealings authorised by this licence;

(f) equipment used for dealings with the GMO must be Decontaminated after use;

(g) preparation and administration of the GMO must be conducted by suitably qualified and trained staff.

(h) the administration site(s) must be covered with an occlusive dressing following administration of the GMO; and

(i) the dressing applied to the administration site(s) must be removed and the administration site cleaned prior to the trial participant leaving the Clinical trial site.

Transport, storage and disposal of the GMOs

33. Unless covered by an NLRD, the licence holder must ensure that transport of the GMOs is conducted only for the purposes of, or in the course of, another dealing permitted by this licence.

34. For the purposes of import or export, and transport between the border and either a Storage facility or a Clinical trial site, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with International Air Transport Association (IATA) shipping classification UN 3245 or UN 3373 [Category B].

35. Transport between a Storage facility and the clinical trial site can also be done consistent with IATA shipping classification UN 3245 or UN 3373 if the GMO is not repackaged at the Storage facility.

36. The licence holder must ensure that transport and storage of the GMO, unless conducted according to Condition 34 or 35, follows these sub-conditions:

(a) GMOs must be contained within a sealed, unbreakable primary and secondary container, with the outer packaging labelled to indicate at least:

iv) that it contains GMOs; and

v) that it contains biohazardous material as designated by a biohazard label; and

vi) the contact details for the licence holder; and

vii) instructions to notify the licence holder in case of loss or spill of the GMO; and

(b) the external surface of the primary and secondary container must be Decontaminated prior to transport; and

(c) procedures must be in place to ensure that GMOs can be accounted for and that a loss of GMOs during transport or storage or failure of delivery can be detected; and

(d) access to the GMOs is restricted to authorised persons for whom Condition 18 or Condition 19 has been met (i.e. the GMOs are within a locked unit or an area which has restricted

access). This includes situations where containers are left for collection in a holding area, or left unattended prior to Decontamination; and

Note: All stored GMOs remain the responsibility of the licence holder.

(e) if the GMO is being transported or stored with a coolant (e.g. dry ice, liquid nitrogen or any other coolant) which will release a gas, a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected; and

Note: When transporting and storing with coolants, it is preferable for coolants to be used outside of the secondary container.

(f) a consolidated record of all GMOs being stored under this condition is maintained and made available to the Regulator upon request; and

(g) for the purposes of transport entirely within a building, where the GMOs are accompanied by an authorised person for whom Condition 19 has been met, Conditions 36(a)vi), 36(a)vii) and 36(c) do not apply.

37. The licence holder must ensure that all GMOs and waste reasonably expected to contain the GMOs are Decontaminated:

(a) prior to disposal, unless the method of disposal is also a method of Decontamination; and

(b) before or upon suspension, cancellation or surrender of the licence, unless covered by another authorisation under the Act, or exported; and

(c) by autoclaving, chemical treatment, high-temperature incineration or any other method approved in writing by the Regulator.

38. Where transport is conducted by External service providers for the purpose of destruction, the licence holder must ensure that the GMO, or waste reasonably expected to contain the GMO, enters the clinical waste stream for Decontamination via autoclaving or high-temperature incineration.

Note: In the event of a spill during transport by an External service provider, compliance with relevant State or Territory legislation and regulations to manage clinical or biohazardous spills is sufficient.

Contingency plans

39. The licence holder must ensure that any person (other than a trial participant) exposed to the GMOs is offered prompt medical advice by a medical practitioner. The medical practitioner must be provided with any relevant information about the GMO.

40. If there is a spill or an unintentional release of the GMO at a Storage facility or Clinical trial site, the following measures must be implemented:

(a) the GMOs must be contained to prevent further dispersal; and

(b) persons cleaning up the GMO must wear appropriate PPE as specified in condition 32(c); and

(c) the exposed area must be Decontaminated with an appropriate chemical disinfectant effective against the GMO; and

(d) any material used to clean up the spill or PPE worn during clean-up of the spill must be Decontaminated; and

(e) the licence holder must be notified as soon as reasonably practicable.

Section 4 Reporting and Documentation

Note: The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR. Notices and reports may be emailed to OGTR.M&C@health.gov.au. A summary of notification and reporting requirements is provided at ***Attachment B****.*

41. The licence holder must notify the Regulator, in writing, of the name and address of each Storage facility before commencement of dealings at that location.

42. At least 14 days prior to first administering the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator, the licence holder must provide the Regulator with a Compliance Management Plan for that Clinical trial site, specifying:

    (a) the name, address and description of the Clinical trial site, including any associated Pharmacies/storage areas/Analytical facilities;

    (b) the role and contact details for key persons responsible for the management of the trial at the site;

    (c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures;

    (d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 15, 16, 43 and 44;

    (e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;

    (f) the person(s) or class of persons administering the GMO;

    (g) where, within the site, the GMO is expected to be administered;

    (h) the expected date of first administration;

    (i) how compliance with Condition 30 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO.

    Note: For the purpose of finding out whether the Act has been complied with, an OGTR inspector may, if entry is at a reasonable time, enter a facility occupied by the licence holder or a person covered by the licence and exercise monitoring powers.

43. For each Clinical trial site, the licence holder must notify the Regulator, in writing, of the end of the clinical trial, no later than 30 days after:

    (a) the final dose being administered; or

    (b) the decision that no further participants will be treated at that site.

44. The licence holder must inform the Regulator as soon as reasonably possible:

    (a) in the event of a loss or spill of the GMO;

    (b) in the event of the exposure of a person other than a trial participant, to the GMO; and

    (c) if a trial participant has not followed the procedures described in the instructions provided by the licence holder.

45. Upon request from the Regulator, the licence holder must provide any signed records or documentation collected under a condition of this licence, within a time period stipulated by the Regulator.

Attachment A

DIR No: 213

Title: Clinical trial with a genetically modified human adenovirus for the treatment of melanoma

Organisation Details Novotech (Australia) Pty Ltd

GMO Description

GMOs covered by this licence:

Human adenovirus C serotype 6 modified by replacement of the hexon variable region (HVR) with the HVR from HAdV-C657, deletion within E1A to prevent replication in healthy cells and partial deletion of E3 replaced with human CD40L

Parent Organisms:

Common Name: *Human adenovirus*

Scientific Name: *Human adenovirus C serotype 6 (HAdV-6 Strain Tonsil 99)*

Modified traits:

Categories: Human therapeutic

Description: The GMO is an attenuated human adenovirus derived from species C serotype 6. It has been modified to preferentially replicate in tumour cells. The E1A contains two deletions that impair binding to p300 and pRB viral replication pathways in healthy cells. The HVR has been replaced with the HVR from HAdV-C657. E3 has been partially deleted and replaced with human CD40L under control of a CMV promoter to increase T-cell responses against infected tumour cells. Modified genes and regulatory sequences are listed in Table 1.

Table 1. Nucleic acid responsible for conferring the modified traits

Identity and modifications	Insert of a transgenic cassette containing: • Cytomegalovirus (CMV) enhancer/promoter • Human CD40L Deletion of: • E3 region • Single site deletions in E1A at positions 1101 and 1107 Replacement of HadV-C6 HVR with HadV-C657 HVR
Function	• CMV – Activates transgene expression • CD40L – immunomodulatory – enhances T-cell response against cells producing CD40L • E3 – deletion reduces immune evasion • E1A – deletions prevent binding to viral replication pathways (p300 and pRB) in healthy cells; while allowing viral replication in tumour cells • C657 HVR – limits effects of pre-existing immunity to HAdV-C6 or HAdV-C5

Attachment B – Summary of reporting requirements*

Prior to the commencement of the trial	**Condition**	**Timeframe for reporting**
The name and address of each Storage facility	41	Before commencement of dealings at that location
A written Compliance Management Plan for each Clinical trial site: (a) the name, address and description of the Clinical trial site, including any associated Pharmacies/storage areas/Analytical facilities; (b) the role and contact details for key persons responsible for the management of the trial at the site; (c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures; (d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 15, 16, 43, and 44; (e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings; (f) the person(s) or class of persons administering the GMO; (g) where, within the site, the GMO is expected to be administered; (h) expected date of first administration; (i) how compliance with Condition 30 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO	42	At least 14 days prior to the first administration of the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator
Information to be provided at any time during the clinical trial	**Condition**	**Timeframe for reporting**
Any additional information related to the health and safety of people and the environment associated with the dealings covered by the licence, or any unintended effects of the dealings authorised by the licence	15(a), (c)	Immediately
Information related to any contravention of the licence by a person covered by the licence	15(b)	Immediately
Any relevant conviction of the licence holder	16(a)	Immediately
Any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country	16(b)	Immediately
Any event or circumstances that would impact the licence holder capacity to meet the licence conditions	16(c)	Immediately

Provide notification to the Regulator, in writing, of the final GMO administration of the last trial participant at each Clinical trial site	43(a)	Within 30 days of the decision to cease GMO administration at that particular Clinical trial site.
Any loss or spill of the GMO, or exposure of a person other than the trial participant to the GMO	44(a), (b)	As soon as reasonably possible
Any event where a trial participant has not followed the procedures described in the instruction provided by the licence holder	44(c)	As soon as reasonably possible
Information to be provided on request by the Regulator		
Information related to the persons covered by the licence	9	Within a timeframe stipulated by the Regulator
Information related to the licence holder's ongoing suitability to hold a licence	17	Within a timeframe stipulated by the Regulator
Copies of signed and dated statements and training records	19	Within a timeframe stipulated by the Regulator
A consolidated record of all GMOs being stored	36(f)	Within a timeframe stipulated by the Regulator
Any signed records or documentation collected under a condition of this licence	45	Within a timeframe stipulated by the Regulator

***** Notifications and documents to be sent to OGTR.M&C@health.gov.au