Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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

Licence No.: DIR 195

Licence Holder: University of Tasmania

Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils

Issued: 14 June 2023

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 195

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

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 Gene Technology Regulations 2001;

   (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.

   ‘APVMA’ means the Australian Pesticides and Veterinary Medicines Authority.

   ‘Decontaminate’ (or ***‘Decontamination’***) means, as the case requires, kill the GMO 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.

   ‘Double contained enclosures’ one or multiple enclosures designed to house the Tasmanian devils, with walls of at least 1.3 meters in height and surrounded by a fence.

   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 Gene Technology Regulations 2001.

'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.

'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 animal for analysis as part of the trial

'Trial site' means areas where the GMO is prepared or used as part of the trial. This includes, but is not limited to, the following:

(a) veterinary sheds where the Tasmanian devils are inoculated with the GMO and biological samples are collected;

(b) double contained enclosures where the Tasmanian devils are kept after receiving the GMO;

(c) facilities used for storage of Samples, material or waste containing the GMO.

Serious adverse event' means any untoward experience that at any dose:

(a) results in death;

(b) is life-threatening;

(c) results in persistent or significant disability or incapacity,

(d) is a congenital anomaly/birth defect in animals

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

General conditions and obligations

Holder of licence

3. The licence holder is University of Tasmania (UTAS).

Remaining an Accredited Organisation

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

Access to trial sites

5. The licence holder must be able to access and control all trial sites to the extent necessary to comply with this licence.

Note: Arrangements to access and control these areas must be notified to the Regulator as part of each Trial site notification (Condition 51(c)).

Validity of licence

6. 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.

Persons covered by this licence

7. The persons covered by this licence are:

   (a) the licence holder, and any employees, agents or External service providers engaged by the licence holder for the import or transport of the GMO; 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.

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 GMO 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 GMO during the period covered by this licence and in accordance with this licence:

    (a) import the GMO

    (b) conduct the following with the GMO:

        i. prepare the GMO for administration to Tasmanian devils;

        ii. administer the GMO to Tasmanian devils by intramuscular (i.m.) or intratumoural (i.t.) injection or by direct instillation into the oral cavity (DIOC);

        iii. collect samples from Tasmanian devils;

        iv. analyse the samples

    (c) transport the GMO;

    (d) dispose of the GMO;

    and the possession (including storage), supply and use the GMO for the purposes of, or in the course of, any of these dealings.

12. Supply of the GMO for the purposes of dealings to any other 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 GMO. This is likely to be an 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.

Monitoring and audits (section 64)

14. If a person is authorised by this licence to deal with the GMO 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 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.

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 another authorisation 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 44(a).

19. If a particular condition, including any variation of it, applies to a person with respect to any dealing, the licence holder must not licence 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 18(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, who are conducting dealings with the GMO.

Note: The licence may be made available electronically.

Limits and control measures

22. The GMO may be administered to a maximum of 22 Tasmanian devils.

23. The preparation and administration of the GMO must be completed within 5 years from the date of issue of the licence.

24. GMO-inoculated Tasmanian devils must be kept in double contained animal enclosures within Trial sites in Tasmania, unless:

(a) they are taken to the veterinary shed within the Trial sites; or

(b) they are relocated according to condition 25.

25. Prior to relocating GMO-inoculated Tasmanian devils, the licence holder must ensure that:

(a) animals to be transferred to an alternative facility show at least 4 consecutive negative test results for the presence of the GMO DNA in faeces, with a minimum of one week between tests; or

(b) animals to be released into the wild:

i) show at least 6 consecutive negative test results for the presence of the GMO DNA in faeces, with a minimum of 4 weeks between tests; and

ii) are negative for the presence of Devil Facial Tumour (DFT) cells.

(c) record of testing results must be kept for the duration of the licence and provided to the Regulator upon request.

Note: This licence condition aims to ensure that animals to be relocated do not contain residual episomes from the GMO.

Trial sites

26. Access to Trial sites must be restricted to persons authorised by the Licence holder.

27. Signs indicating the presence of the GMO must be displayed at all entrances to the Trial sites.

28. Animal enclosures must be:

(a) constructed to prevent the escape of Tasmanian devils, including via climbing and digging; and

(b) contained within a security fence.

29. Unbaited traps (i.e. artificial dens) must be placed outside of the perimeter security fence for the duration of the trial.

Preparation and administration of the GMO

30. Administration of the GMO to Tasmanian devils must not commence prior to approval by an Animal Ethics Committee and the APVMA.

31. Preparation and administration of the GMO must be conducted by suitably qualified and trained staff.

32. The following activities must occur in a veterinary shed within a Trial site:

(a) preparation of the GMO for administration to Tasmanian devils; and

(b) administration of the GMO to Tasmanian devils; and

(c) collection of blood and swab Samples.

Note: Before any of these activities take place, the details of each Trial site must have been notified to the Regulator in accordance with Condition 51.

33. The licence holder must ensure that Tasmanian devils are appropriately anaesthetised and kept under anaesthesia during the administration of the GMO and the collection of blood and swab Samples.

Conditions related to the conduct of the dealings

34. Animals must be able to be individually identified.

35. For at least 2 weeks following administration of the GMO via DIOC or i.t injection, the licence holder must ensure that:

(a) animals are captured using PVC traps, except when an animal requires immediate veterinary care; and

(b) animals requiring immediate veterinary care can be captured by hand as long as personnel wear elbow length leather gloves;

(c) the drinking water is replaced at least 3 times per week and waste water Decontaminated; and

(d) faeces are collected from the enclosures daily.

36. Conditions that apply to dealings with GMOs do not apply to:

(a) faecal Samples, oral and anal swabs collected from Tasmanian devils at least 2 weeks after administration of the GMO via DIOC or i.t. injection;

(b) blood Samples collected from Tasmanian devils at least 7 days after administration of the GMO via i.m. injection; and

(c) other Samples, materials and waste, that are reasonably expected not to contain the GMO. Upon request from the Regulator, the licence holder must provide a written justification for this expectation.

Note: This licence condition aims to ensure that Samples, materials and waste, that are reasonably expected to contain viable GMOs are properly handled and Decontaminated.

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

(a) ensures containment of the GMO; and

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

(c) minimises the exposure of persons conducting the dealings to the GMO.

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.

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

Work practices at Trial sites

39. For the purposes of Condition 37, the licence holder must ensure that the work practices and behaviours within a Trial site must include, but are not limited to, the following:

(a) persons preparing or administering the GMO, or collecting blood, oral or anal swab Samples that are reasonable expected to contain the GMO must wear personal protective equipment (PPE), including but not limited to gowns, gloves, eye protection and a surgical face mask;

(b) for least for two weeks following the administration of the GMO to Tasmanian devils:

i) persons entering the enclosure of GMO-inoculated animals must wear PPE, including but not limited to waterproof footwear, gloves and for dealings likely to generate aerosol (i.e. Decontamination of drinking water), eye protection and surgical face mask; and

ii) PPE listed in 39(a) and 39(b)i), including footwear and leather gloves if exposed to the GMO, must be Decontaminated.

(c) all work surfaces must be Decontaminated before and after conducting dealings authorised by this licence;

(d) all equipment must be Decontaminated after conducting dealings with the GMO;

Work practices at a Certified PC2 laboratory

40. Analysis of biological Samples must be conducted in PC2 laboratory facilities at University of Tasmania.

41. Persons analysing biological Samples reasonably expected to contain the GMO must wear personal protective equipment (PPE), including but not limited to gowns, gloves and, unless working in a biosafety cabinet or negative pressure pharmaceutical isolator, eye protection and a surgical face mask.

Transport, storage and disposal of the GMO

42. The licence holder must ensure that transport of the GMO is conducted only for the purposes of, or in the course of, another dealing authorised by this licence, or for supply in accordance with Condition 12.

43. For the purposes of import and transport between the border and either a Storage facility, the University of Tasmania or a Trial site, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with IATA shipping classification UN 3373/3245.

44. The licence holder must ensure that transport and storage of the GMO, biological Samples, material or waste reasonably expected to contain GMOs, between certified PC2 laboratory facilities at University of Tasmania and the Trial sites and, unless conducted according to condition 43,follows these sub-conditions:

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

        i) that it contains GMOs; and

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

        iii) the contact details for the licence holder; and

        iv) instructions to notify the licence holder in case of loss or spill of the GMOs; and

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

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

    (d) access to the GMO is restricted to authorised persons for whom Condition 18 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, and the GMOs are accompanied by authorised persons for whom Condition 13 has been met, Conditions 44(a)iii), 44 (a)iv) and 44(c) do not apply.

45. The licence holder must ensure that the facilities used for storage of Samples, material or waste containing the GMO are locked and restricted to authorised persons for whom Condition 18 or 19 has been met.

46. The licence holder must ensure that all GMOs, biological Samples, material and waste reasonably expected to contain the GMO 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; and

(c) by autoclaving, chemical treatment or high-temperature incineration.

(d) In the event of a Tasmanian devil dies from DFTD during the trial, its remains must be Decontaminated by autoclaving at 121 ℃ for at least 2 hours.

Note: This condition also applies to waste drinking water for the first 2 weeks following administration of the GMO to Tasmanian devils via DIOC or i.t injection.

Contingency plans

47. The licence holder must ensure that any person exposed to the GMO is offered prompt medical attention. The clinician must be provided with any relevant information about the GMO.

48. If there is a spill or an unintentional release of the GMO at a Trial site, the following measures must be implemented:

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

(b) persons cleaning up the GMO must wear PPE including gowns, gloves, eye protection and surgical face mask; 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 possible.

49. If a GMO-inoculated devil escapes within or outside the security fence, the animal must be captured and returned to its enclosure.

50. If there is an unintentional release of the GMO or devils containing the GMO from containment, or a person is exposed to the GMO, the licence holder must ensure that the following persons must be notified as soon as reasonably possible:

(a) the UTAS IBC; and

(b) the Regulator.

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****.*

51. At least 14 days prior to administering the GMO, at each Trial site, the licence holder must notify the Regulator, in writing, of:

    (a) the commencement of the trial; and

    (b) the location of the trial; and

    (c) the details of how the licence holder will access and control the Trial site, in accordance with Condition 5

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

    (a) the final dose being administered; or

    (b) the decision that no further doses of the GMO will be administered at that site.

53. The licence holder must inform the Regulator as soon as reasonably possible in the event of an animal experiencing a serious adverse event which may be related to the GMO;

54. 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: 195

Full Title: Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils

Organisation Details

Postal address: University of Tasmania

Private Bag 1

Hobart TAS 7001

Phone No: (03) 6226 2999

Accreditation No: Accr 051

GMO Description

GMOs covered by this licence

The GM vaccine contains a replication defective Human Adenovirus serotype 5 modified by the deletion or introduction of the genes or genetic elements listed in Table 1 below.

Parent Organism

Common Name: Human Adenovirus serotype 5

Scientific Name: Human Adenovirus

Modified traits

Category: Veterinary

Description: The GMO, known as WIVA20, is a replication defective Human Adenovirus serotype 5 modified to produce proteins capable of inducing an immune response against devil facial tumour cells.

Purpose of the dealings with the GMO

The purpose of the proposed trial is to evaluate the immunogenicity, safety and efficacy of a genetically modified vaccine in Tasmanian devils for the prevention and/or treatment of devil facial tumour disease.

Table 1. Nucleic acid responsible for conferring the modified traits

Genetic modifications	
Source, identity, nature of modification	**Modified trait description**
• Deletion of viral early-transcribed region 1 (E1)	to render virus unable to multiply.
• Deletion of viral early-transcribed region 3 (E3)	to increase host immune response to the virus.
• WIVA20 Antigen 1: - Element X	to induce an immune response
• WIVA20 Antigen 2:	
- Polypeptide neoantigen (PPNA)	to induce an immune response
- Elements Y and Z	to facilitate the transport of the PPNA to the desired location in the cell
- Monomeric Green Lantern (mGL)	to facilitate the visualisation of PPNA expressed in GMO-transduced cells

Purpose of the dealings with the GMOs:

To conduct trials assessing the immunogenicity, safety and efficacy of a genetically modified vaccine in Tasmanian devils for the prevention and/or treatment of devil facial tumour disease.

Route of administration of the GMOs

The GMO would be administered via i.m. or i.t. injection or via direct instillation into the oral cavity (DIOC).

Attachment B – Summary of reporting requirements*

Prior to the commencement of the trial	**Condition**	**Timeframe for reporting**
Expected date of first administration at each trial site	51(a)	At least 14 days prior to the first administration of the GMO at each trial site.
Location of the trial	51(b)	
Details of how the licence holder will access and control the trial site	51(c)	
Information to be provided at any time during the 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)	As soon as the licence holder becomes aware
Information related to any contravention of the licence by a person covered by the licence	15(b)	As soon as the licence holder becomes aware
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
Any unintentional release of the GMO or Tasmanian devils containing the GMO from containment, or exposure of a person to the GMO.	50(b)	As soon as reasonably possible after becoming aware of the event
Provide notification to the Regulator, in writing, of the final GMO administration at each trial site	52	Within 30 days of the decision to cease GMO administration at that particular trial site.
Any Serious adverse event which may be related to the GMO	53	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	18	Within a timeframe stipulated by the Regulator
A consolidated record of all GMOs being stored	44(f)	Within a timeframe stipulated by the Regulator
Any signed records or documentation collected under a condition of this licence	54	Within a timeframe stipulated by the Regulator

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