Australian Government

National Archives of Australia

Records Authority

2018/00115487

Department of Health

Gene Technology Regulation

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INTRODUCTION

The Department of Health (the agency) and the National Archives of Australia have developed this records authority to set out the requirements for keeping or destroying records for the core business area of Gene Technology Regulation. It represents a significant commitment on behalf of the Department of Health to understand, create and manage the records of its activities.

This authority is based on the identification and analysis of the business of the Department of Health. It takes into account the agency's legal and organisational information management requirements, and the interests of stakeholders, the agency and the National Archives.

The authority sets out those records that need to be retained as national archives and specifies the minimum length of time that temporary records need to be kept. This authority gives the Department of Health permission under the *Archives Act 1983*, for the destruction of the temporary records described after the minimum retention period has expired. Retention periods for these temporary records are based on: an assessment of business needs; broader organisational accountability requirements; and community expectations, and are approved by the National Archives on the basis of information provided by the agency.

As changes in circumstances may affect future information management requirements, the periodic review of this authority is recommended. All amendments must be approved by the National Archives.

APPLICATION OF THIS AUTHORITY

1. This authority is to be used to determine how long records must be kept. Records are matched to the relevant core business and records class in the authority.
    - Where the minimum retention period has expired and the records are not needed for Departmental business they should be destroyed as authorised in this authority;
    - Records that have not reached the minimum retention period must be kept until they do; and
    - Records that are identified as 'retain as national archives' are to be transferred to the National Archives for preservation.
2. This authority should be used in conjunction with general records authorities such as:
    - the Administrative Functions Disposal Authority (AFDA) and/or AFDA Express issued by the National Archives to cover business processes and records common to Australian Government agencies; and
    - General Records Authority (31) - Destruction of source or original records after digitisation, conversion or migration (2015).
3. The normal administrative practice (NAP) provision of the *Archives Act 1983* gives agencies permission to destroy certain records without formal authorisation. This usually occurs where records are duplicated, facilitative or for short-term use only. NAP does not replace arrangements agreed to in this authority but can be used as a tool to assist in identifying records for destruction together with an agency's records authority or authorities, and with AFDA and AFDA Express. The National Archives recommends that agencies develop and implement a NAP policy. Advice and guidance on destroying records as a normal administrative practice and on how to develop a NAP policy is available from the National Archives' website at www.naa.gov.au.
4. Records that are reasonably likely to be needed as evidence in a current or future judicial proceeding or are subject to a request for access under the *Archives Act 1983,* the *Freedom of Information Act 1982* or any other relevant act must not be destroyed until the action has been completed.
5. Records subject to a disposal freeze must not be destroyed until the freeze has been lifted. Further information about disposal freezes and whether they affect the application of this authority is available from the National Archives website at www.naa.gov.au
6. Where the method of recording information changes (for example from a manual system to a digital system, or when information is migrated from one system to a new system) this authority

can still be applied, providing the records document the same core business. The information must be accessible for the period of time prescribed in this authority. The Department of Health will need to maintain continuing access to the information, including digital information, for the periods prescribed in this records authority or until the information is transferred into the custody of the National Archives.

7. In general, retention requirements indicate a minimum period for retention. The Department of Health may extend minimum retention periods if it considers that there is an administrative need to do so, without further reference to the National Archives. Where the Department of Health believes that its accountability will be substantially compromised because a retention period or periods are not adequate, it should contact the National Archives for review of the retention period.
8. Records coming within 'retain as national archives' classes in this authority have been determined to be part of the archival resources of the Commonwealth under section 3C of the *Archives Act 1983*. The determination of Commonwealth records as archival resources of the Commonwealth obliges agencies to transfer the records to the National Archives when they cease to be current and, in any event, within 15 years of the records coming into existence, under section 27 of the *Archives Act 1983*.
9. Records in the care of agencies should be appropriately stored, managed and preserved. Agencies need to meet this obligation to ensure that the records remain authentic and accessible over time. Under Section 31 of the *Archives Act 1983*, access arrangements are required for records that become available for public access including those records that remain in agency custody.
10. Appropriate arrangements should be made with the National Archives when records are to be transferred into custody. The National Archives accepts for transfer only those records designated as national archives. Records created digitally after 1 January 2016 can be transferred in digital formats only.
11. Advice on how to use this authority is available from the Department of Health information manager. If there are problems with the application of the authority that cannot be resolved, please contact the National Archives.

CONTACT INFORMATION

For assistance with this authority or for advice on other information management matters, please contact National Archives' Agency Service Centre.

AUTHORISATION

RECORDS AUTHORITY 2018/00115487

Person to whom notice of authorisation is given:	Ms Glenys Beauchamp PSM Secretary Department of Health GPO Box 9848 Canberra ACT 2601
Purpose:	Authorises arrangements for the disposal of records in accordance with Section 24(2)(b) of the *Archives Act 1983.* Determines records classed as 'retain as national archives' in this records authority to be part of the archival resources of the Commonwealth under section 3C of the *Archives Act 1983*.
Application:	All core business records relating to Gene Technology Regulation

This authority gives permission for the destruction, retention or transfer to the National Archives of Australia of the records described. This authority will apply only with the consent of the agency currently responsible for the business documented in the records described.

Authorising Officer	**Date of issue:**
Linda Macfarlane A/g Assistant Director-General National Archives of Australia	18 May 2018

GENE TECHNOLOGY REGULATION

The core business of protecting the health and safety of people, and the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

Notes:

The authority for the regulation of gene technology is provided by relevant legislation, currently the *Gene Technology Act 2000* (the Act), *Gene Technology Regulations 2001* (the Regulations) and the corresponding state and territory laws. It is a nationally consistent scheme of regulation administered by the Gene Technology Regulator (the Regulator).

The Act defines certain 'dealings' (work with) in relation to GMOs that require authorisation by the Regulator. These 'dealings' are to conduct experiments, make, develop, produce or manufacture, breed, propagate, grow, raise or culture, import, transport and dispose of GMOs.

The categories of authorisations for dealings with GMOs under the Act are:

- Dealings included on the GMO Register
- Dealings involving intentional release into the environment
- Dealings *not* involving intentional release into the environment (eg dealings with GMOs in contained facilities)
- Emergency Dealing Determinations (EDD)
- Exempt dealings (in contained facilities)
- Inadvertent dealings
- Notifiable Low Risk Dealings (NLRD) (in contained facilities).

Core activities include:

- developing and providing advice and information about GMOs, GM products, and regulation of GMOs to relevant stakeholders, such as other regulatory agencies and the public;
- advising the Minister on determinations relating to dealings with GMOs in emergencies (Emergency Dealing Determinations or EDDs). Includes advice on imposing conditions, variations, suspensions and revocations of EDDs;
- advising the Ministerial Council on declaring a dealing with a GMO to be a notifiable low risk dealing (NLRD) or an exempt dealing. Includes recommending amendments to the regulations;
- developing draft policy principles and policy guidelines as requested by the Ministerial Council;
- providing advice and reports to the Ministerial Council on the operations of the Regulator, the Gene Technology Technical Advisory Committee and the effectiveness of the legislative framework for the regulation of GMOs including advice in relation to possible amendments of the relevant legislation;
- negotiating, establishing, reviewing and managing national and international agreements and contracts (including contracts under seal), memorandums of understanding (MoU), conventions, instruments and deeds of standing offers relating to the regulation of gene technology;
- issuing GMO licences. Includes assessing applications, preparing risk assessments and risk management plans, making decisions on licence and licence conditions, issuing, refusing, suspending, varying, surrendering or cancelling of licences;
- certifying facilities to specified containment levels in accordance with guidelines. Includes imposing conditions of certification, variation, transfer, suspension or cancellation of certifications;
- accrediting organisations as 'accredited organisations'. Includes imposing conditions of accreditation, variation, suspension or cancellation of accreditations;
- deciding on applications for the protection of confidential commercial information. Includes making and revoking of declarations;
- enforcing compliance with the legislation and the regulations by appointing inspectors and carrying out inspections, audits or investigations relating to breaches or potential breaches of

licence conditions. Includes monitoring conditions of licence and certified facilities for compliance in relation to dealings with GMOs, giving directions to licence holders, monitoring equipment at premises, searching premises and seizing equipment and goods, monitoring warrants and managing and disposing of forfeited objects;
- maintaining the GMO Register. Includes conducting risk assessment of dealings with a GMO, any conditions to which a GMO dealing is subjected, determination on dealings with GMOs for including in the GMO register by legislative instrument, variation of GMO register by legislative instrument - remove a dealing, revoke or vary conditions or impose additional conditions;
- maintaining the Record of GMO Dealings (the GMO Record);
- monitoring the international practice in relation to the regulation of GMOs;
- developing and implementing policies, strategies, codes of practice, plans and procedures in relation to GMOs;
- developing products (eg application forms, guidance materials, fact sheets etc) and tools to support gene technology regulation;
- developing and issuing technical and procedural guidelines, in relation to GMOs (eg on certification of facilities and accreditation of organisations);
- undertaking or commissioning research in relation to gene technology trends, risk assessment and the biosafety of GMOs;
- reviewing of notifiable low risk dealings and exempt dealings;
- reviewing decisions made by the Regulator under the gene technology legislation, when appealed; and
- promoting the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies.

The performance of the core function is supported by **general activities** such as**:**
- preparing and presenting addresses and speeches;
- establishing, managing and participating in committees, meetings, working groups, forums, assessment panels, task forces and other bodies;
- arranging and attending conferences;
- liaising, consulting and exchanging information with relevant stakeholders, such as Commonwealth, State and Territory agencies, or with international organisations;
- internal and external reporting, including preparing annual reports to the relevant Minister and the Federal Parliament; and
- reviewing policies, strategies, codes of practice, plans, procedures, guidelines etc.

Cross references to other General Records Authorities

For statutory and non-statutory gene technology advisory bodies, including the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee, use General Records Authority 26 – ADVISORY BODIES.

Cross references to AFDA Express Records Authority

For the preparation of budget estimates, budget proposals, cost modelling, and making financial transactions, use FINANCIAL MANAGEMENT.

For records of financial transactions associated with investigations and seizures, including the sale of seized objects, use FINANCIAL MANAGEMENT.

For advice to the Minister, ministerial submissions, and the development of legislation, use GOVERNMENT RELATIONS.

For the procurement of goods and services, including contractors and consultants, use PROCUREMENT.

For the publication and distribution of agency publications and for published conference proceedings, use PUBLICATION.

GENE TECHNOLOGY REGULATION

Class no	Description of records	Disposal action
62430	Records documenting: • development, implementation and review of national or high level policies, policy principles, policy guidelines and codes of practice in relation to genetically modified organisms (GMOs) and their regulation. Includes final version and supporting materials obtained through liaison and consultation with relevant Australian and international stakeholders; • development, implementation and review of products (eg application forms, guidance materials, fact sheets etc), product guidelines and tools in relation to GMOs and gene technology regulation. Includes final version and supporting materials obtained through liaison and consultation with relevant stakeholders; • high-level advice and information provided to or received from stakeholders (eg other regulatory agencies, regulated organisations, the public) in relation to GMOs and GM products; • Emergency Dealing Determinations (EDD). Includes risk assessment, consultations with Commonwealth, State and Territory agencies, Minute to the Minister, Minister's determination or making of the regulatory instrument. Also includes conditions, variations, suspensions or revocations of EDDs; *For the development of regulations for exempt dealings and notifiable low risk dealings with GMOs, use class 62434.* • advice provided to the Ministerial Council about the operations of the Regulator and the effectiveness of the legislative framework for the regulation of GMOs; *For advice provided to the Ministerial Council on exempt dealings and notifiable low risk dealings, use class 62434* • international and national agreements and contracts (including contracts under seal), MoUs, conventions, instruments and deeds of standing offer relating to the international regulation of gene technology; *For signed agreements and contracts relating to the national regulation of gene technology, use classes 62431 to 62433.* • high-level liaison, consultation and other forms of collaboration with Commonwealth, State and Territory agencies, or with international organisations, on the regulation of gene technology, the regulation of GMOs, and the harmonisation of risk assessments relating to GMOs; • external and high level internal committees, meetings, working groups, forums, assessment panels, task forces and other bodies relating to gene technology regulation, where the agency provides secretariat, is the Australian Government's main representative, or plays a prominent or central role (eg Gene Technology Technical Advisory Committee). Includes documents establishing the committees, working groups, etc., agenda, final version of minutes, reports, briefing notes and tabled papers; • issuing of GMO licences. Includes receiving and assessing licence applications, imposing licence conditions, issuing, refusing, suspending, cancelling, varying, surrendering or transferring of licences. Also includes preparing risk assessments and risk management plans. Excludes the monitoring of licensing system; *For the monitoring of licensing system, use class 62434.*	Retain as national archives

GENE TECHNOLOGY REGULATION

Class no	Description of records	Disposal action
	• certifying facilities to particular containment levels. Includes receiving and assessing applications, imposing conditions of certification, refusing, varying, suspending, cancelling or transferring of certification; • accrediting organisations. Includes receipt and assessing of applications, imposing conditions of accreditation, refusing, varying, suspending or cancelling the accreditation; • inspections, audits or investigations relating to breaches or potential breaches of licence conditions that are high profile or controversial, or are expected or found to have a broad impact on the public or the environment, or which relate to changes to agency policy or legislation. Includes appointing of inspectors, obtaining and executing warrants to conduct searches, seizing and securing equipment and goods and making applications to extend seizing periods; *For all other inspections, audits or investigations into breaches or possible breaches of licence conditions, use class 62434.* • monitoring and documenting of international practices in relation to the regulation of GMOs. Includes supporting research; • findings or outcomes of research into gene technology trends (eg use of new techniques), including research in relation to the risk assessment and the biosafety of GMOs; • reviews of precedent-setting decisions made by the Regulator under gene technology legislation, when appealed; • master version of agency publications produced to support gene technology regulation. Includes guidelines, handbooks, information bulletins and fact sheets; • reports, papers and proceedings of national gene technology regulation conferences hosted by the agency; and • final version of speeches and addresses presented by the portfolio Minister or senior agency staff in support of the Regulator's core business. GMO Register. Includes description of dealings determined by the Regulator to be included on the GMO Register, conditions to which the dealings are subject, and variations to the dealings; Record of GMO Dealings (the GMO Record). Includes all dealings in Australia that involve GMOs, and information, other than records in classes 62434 or 62438.	
62431	Signed agreements or contracts executed under seal prior to 15 November 2005 with individuals, organisations, non-government agencies and companies relating to the regulation of gene technology, and supporting records: Western Australia. Excludes agreements and contracts covered under class 62430.	Destroy 21 years after completion or other termination of agreement
62432	Signed agreements or contracts executed under seal with individuals, organisations, non-government agencies and companies relating to the regulation of gene technology, and supporting records: Victoria and South Australia. Excludes agreements and contracts covered under class 62430.	Destroy 15 years after completion or other termination of agreement

GENE TECHNOLOGY REGULATION

Class no	Description of records	Disposal action
62433	Signed agreements or contracts executed under seal with individuals, organisations, non-government agencies and companies relating to the regulation of gene technology, and supporting records: New South Wales, Western Australia (from 15 November 2005), Queensland, Australian Capital Territory, Northern Territory and Tasmania. Excludes agreements and contracts covered under class 62430.	Destroy 12 years after completion or other termination of agreement
62434	Records documenting: • advice to Ministerial Council on possible amendments to the regulations for exempt dealings and notifiable low risk dealings with GMOs; • development of regulations for exempt dealings and notifiable low risk dealings with GMOs; • assessments and lists of notifiable low risk dealings for GMOs posing negligible risks, providing certain management conditions are met; • monitoring of compliance with conditions of a licence and or a certified facility to deal with GMOs and monitoring accredited organisations; and • inspections, audits or investigations into breaches or possible breaches of conditions of authorisations not covered under class 62430. Includes appointing of inspectors, obtaining and executing warrants to conduct searches, seizing and securing equipment and goods and making applications to extend seizing periods.	Destroy 20 years after expiry or termination of authorisation of dealings
62435	Records documenting management and eventual disposal (including by sale) of objects that were the subject of a court-ordered forfeiture.	Destroy 20 years after action completed
62436	Records of legislated gene technology regulation activities, other than those covered in classes 62430-62435, relating to: • provision of advice; • management of internal or external committees; • management of delegations; • development of routine internal procedures and guidelines for the regulation of gene technology; • development of operational policies; • preparation of routine internal and external reports; and • review of systems.	Destroy 15 years after action completed
62437	Applications for the protection of confidential commercial information and declaration by the Regulator of confidential commercial information.	Destroy after declaration of confidentiality has been revoked
62438	Records documenting: • routine operational administrative tasks supporting the core business; and • gene technology regulation activities, other than those covered in classes 62430 to 62437.	Destroy 7 years after action completed