Australian Government

NATIONAL ARCHIVES OF AUSTRALIA

Records Authority

2017/00330754

Department of Health

Health Products Regulation Group

Drug Control Regulation and Administration, and Therapeutic Goods Regulation

This is an accurate reproduction of the authorised records authority content, created for accessibility purposes

2017

Copyright

Attribution

Accessibility

This is an accurate reproduction of the authorised records authority content, created for accessibility purposes.

Contact Us

Enquiries relating to copyright or accessibility should be made through the Agency Service Centre.

CONTENTS

INTRODUCTION

The Department of Health, the Heath Products Regulation Group (HPRG) 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 areas of Drug Control Regulation and Administration, and Therapeutic Goods Regulation. It represents a significant commitment on behalf of the Department 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. 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 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 supersedes records disposal authority (RDA) 1289 (1998). The superseded records authority cannot be used by the Department of Health to sentence records after the date of issue of this authority.
2. 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 agency 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.
3. 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).
4. 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.
5. 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.
6. 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.
7. Where the method of recording information changes (for example from an analogue 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 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.

8. In general, retention requirements indicate a minimum period for retention. The Department 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 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.
9. 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*.
10. 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.
11. 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 must be transferred in digital formats only.
12. Advice on how to use this authority is available from the Department information management section. 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 2017/00330754

Person to whom notice of authorisation is given:	Ms Glenys Beauchamp 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 Drug Control Regulation and Administration, and Therapeutic Goods 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:**
Teressa Ward Assistant Director-General National Archives of Australia	20 November 2017

DRUG CONTROL REGULATION AND ADMINISTRATION

The core business of administering a regulatory framework for drug control, including the import and export of controlled substances in accordance with international drug conventions such as the United Nations Single Convention on Narcotic Drugs 1961 and relevant legislation such as the *Narcotic Drugs Act 1967*, *Customs (Prohibited Imports) Regulations 1956*, and the *Customs (Prohibited Exports) Regulations 1958*. Includes manufacturing controls and domestic transaction and border controls for drugs such as narcotics, psychotropic substances, antibiotics and androgenic/anabolic substances.

The **core activities** include:

- managing the process of licensing including assessing applications, variations, authorising, issuing and cancelling permits, and licences;
- managing appeals against decisions;
- product compliance monitoring and intelligence;
- compliance investigation and enforcement actions, including litigation;
- reviewing and revising, regulatory decisions and principles;
- referring matters to external parties such as law enforcement agencies;
- collecting data relating to domestic drug movements, manufacture and consumption;
- internal and external reporting including to State and Territory governments and the International Narcotic Control Board (INCB);
- reporting;
- negotiating and establishing agreements; and
- managing submissions and representations to peak industry bodies.

The performance of the core business is supported by **general activities** such as:

- developing, implementing and reviewing processes, systems and procedures;
- addresses (presentations);
- providing and receiving advice and other forms of information;
- managing audits;
- authorising delegations of power and actions;
- managing committees and meetings;
- handling enquiries and complaints;
- liaising with stakeholders;
- planning organisational objectives;
- developing operational policies and procedures;
- creating and managing data bases and datasets;
- project management;
- research;
- risk management; and
- managing visits.

Cross references to AFDA Express records authority

For minutes of statutory Advisory Council and Standing Committee meetings, use ADVISORY BODIES.

For advice to the Minister, use GOVERNMENT RELATIONS.

DRUG CONTROL REGULATION AND ADMINISTRATION

For processing licence and permit payments, use FINANCIAL MANAGEMENT.

For draft and producing publications for external use, use PUBLICATIONS.

For staff travel, use PERSONNEL.

For signed deeds of release, deeds of indemnity and other similar agreements, use LEGAL SERVICES.

For the preparation and passage of legislation through Parliament, use STRATEGIC MANAGEMENT.

Cross references to other records authorities

For the management of contracts and deeds under seal, use GRA 36 – CONTRACTS UNDER SEAL/DEEDS.

Cross references to other areas of this records authority

For registering controlled drugs, use THERAPEUTIC GOODS REGULATION.

For regulating the subsequent use of drugs and controlled substances approved for import or manufacture, use THERAPEUTIC GOODS REGULATION.

For regulating the import, export, supply and manufacture of therapeutic goods, use THERAPEUTIC GOODS REGULATION.

Class no	Description of records	Disposal action
62394	Records documenting: • high-level agreements with international and other stakeholders e.g. intergovernmental authorities. Includes: advice; memorandums of understanding; bilateral agreements; cooperative arrangements and other formal agreements; and input on drafting of international conventions and agreements; • appeals made against controversial decisions, where precedents are set, or which are significant or create intense media interest. Includes appeals to higher authorities such as the Administrative Appeals Tribunal and the Federal Court; • providing and receiving high-level advice. Includes final versions, stakeholder submissions, position papers, briefs and supporting research; • investigations and enforcement of penalties in serious, provocative, or controversial cases of industry non-compliance with legislative requirements or principles in relation to drug control administration, such as those that attract parliamentary or significant public interest; • litigation and legal proceedings including civil, criminal, administrative or regulatory proceedings related to delegated responsibilities of enforcing powers relating to significant investigative and enforcement matters; that have far-reaching corporate, social, economic, environmental, national or international implications, where a precedent is set, creates intense media interest, is controversial or results in major changes to policy, procedures or legislation; • developing national and high-level reports to the Minister, Agency Heads, key international partners, stakeholders, and interest groups. Includes final versions, major drafts, stakeholder consultations and supporting research such as data sets; • representation received or made from or to regional and international peak industry bodies, international governments or	Retain as national archives

DRUG CONTROL REGULATION AND ADMINISTRATION

Class no	Description of records	Disposal action
	non-government bodies, leading community interest groups, recognised influential stakeholders or individuals concerning issues of a contentious nature relating to the regulation and administration of drug control; and • submissions relating to the regulation and administration of drug control, including regulatory policies, where the issue is controversial, or has significant legal, social, economic or international implications. Includes final versions of research and associated statistical reports and working papers.	
62395	Records documenting: • the receipt, processing and assessment of applications for the import, manufacture and cultivation of controlled substances. Includes issuing statutory licences and permits for approved applications; • drug control administration activities other than those covered in class 62394; and • routine operational administrative tasks supporting the core business.	Destroy 7 years after action completed

THERAPEUTIC GOODS REGULATION

The core business of regulating the import, export, manufacture, supply and advertising of therapeutic products in accordance with legislation such as the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*, Includes biological, complementary, prescription, and non-prescription medicines, orphan drugs, medical devices, blood, blood products and tissues.

The **core activities** include:

- developing, implementing and evaluating policies, strategies and guidelines;
- evaluation of applications including pre-market assessments of medical devices and issuing licences, import and export permits and certifications;
- managing appeals against decisions;
- post-market compliance monitoring and enforcement of standards. Includes inspections, desktop audits, regulatory education, complaints, compliance undertakings, suspensions and cancellations;
- managing recalls;
- managing committees and meetings;
- developing education programs;
- preparing and delivering presentations;
- providing and receiving advice and other forms of information;
- negotiating, establishing and managing agreements, including joint ventures;
- fee setting;
- performing laboratory testing and sampling;
- establishing, implementing and reviewing codes, and standards, including those covering investigations, enforcement and legal proceedings;
- referring matters to external parties such as the statutory Advisory Committee on Chemicals Scheduling;
- registration of approved listings, applications and conformity assessments. Includes compiling and maintaining the public register of therapeutic goods;
- providing advice and input to the development of National and International standards relating to the specifications, performance and characteristics of therapeutic goods;
- managing submissions and representations from peak industry bodies; and
- consultations with peak industry bodies.

The performance of the core business is supported by **general activities** such as:

- managing internal and external audits;
- authorising delegations of powers and actions;
- developing, implementing and reviewing processes, systems and procedures designed to support the core business;
- complaints handling;
- arranging or attending conferences;
- handling enquiries for information;
- liaising with stakeholders;
- reporting, research and reviewing;
- risk management; and
- managing visits.

THERAPEUTIC GOODS REGULATION

Cross references to AFDA Express records authority

For advice and submissions to the Minister, use GOVERNMENT RELATIONS.

For processing registration payments for therapeutic goods licences, certificates and permits, use FINANCIAL MANAGEMENT.

For maintaining quality management system documentation, use INFORMATION MANAGEMENT.

For internal and external legal advice relating to non-compliance of legislation, use LEGAL SERVICES.

For draft and producing publications for external use, use PUBLICATIONS.

For staff travel, use PERSONNEL.

For planning organisational objectives and reporting against the government's Regulator Performance Framework (RPF) use STRATEGIC MANAGEMENT.

Cross references to other areas of this records authority

For administering a drug control regulatory framework in accordance with international conventions and Australian regulations for the import and export of controlled substances such as narcotic drugs, use DRUG CONTROL ADMINISTRATION.

Cross references to other records authorities

For the management of contracts and deeds under seal, use GRA 36 – CONTRACTS UNDER SEAL/DEEDS.

For establishment and management of statutory Advisory Committees and Councils, use GRA 27 - ADVISORY BODIES.

Class no	Description of records	Disposal action
62396	Records documenting: • Summary records of successful applications including the Australian Register of Therapeutic Goods for listed or registered therapeutic goods. Includes additions, variations, suspensions, cancellations, recalls, exemptions, notifications, event and audit logs, and data dictionaries; [For issuing password certificates and tokens, including requests to access the national register, use Class 62399] • appeals or reviews of decisions made by the agency that: are precedent setting, controversial or of significant public interest; or, result in major changes to agency policy or programs. Includes appeals to higher authorities such as the Administrative Appeals Tribunal and the Federal Court; • providing and receiving high-level advice. Includes final versions, stakeholder submissions, position papers, briefs and supporting research; • high-level agreements and joint ventures with international or other intergovernmental stakeholders. Includes: memoranda of understanding; bilateral agreements; cooperative arrangements and other formal agreements; and provision of input on drafting of international conventions or agreements; • high-level internal and external committees, working groups and other bodies where the agency provides the secretariat, is the Australian Government's main representative, or plays a prominent or central role. Includes establishment documentation, agenda, final versions of minutes, reports, briefing notes and tabled papers;	Retain as national archives

THERAPEUTIC GOODS REGULATION

Class no	Description of records	Disposal action
	• development and review of codes and standards; • master set of education program materials; • master set of agency publications; • investigations, reviews, and enforcement of penalties in serious, provocative, or controversial cases of industry non-compliance with codes, standards and regulatory requirements in relation to therapeutic goods regulation, such as those that attract parliamentary or significant public interest, or result in recall action. Includes supporting documentation from clinical or scientific tests of therapeutic goods; • representations, engagement and consultation with regional and international peak industry bodies, international governments or non-government bodies, leading community interest groups, recognised influential stakeholders or individuals concerning issues of a contentious nature relating to regulation of therapeutic goods; • litigation and legal proceedings including civil, criminal, administrative or regulatory proceedings related to the agency's delegated responsibilities of enforcing powers under legislation which relate to significant investigative and enforcement matters that have far-reaching corporate, social, economic, environmental, national or international implications, where a precedent is set, is controversial or creates intense media interest or results in major changes to policy, procedures or legislation; • developing, implementing and reviewing national and high-level policies, strategies, plans, frameworks and standards. Includes final versions, policy proposals, supporting research, policy costings, briefs, major drafts, minutes and related correspondence; • developing national and high-level reports to the Minister, Agency Heads, key international partners stakeholders and interest groups. Includes final versions, major drafts, stakeholder consultations and supporting research; • national and high-level reviews, including sector-wide and major internal reviews. Includes final review reports, major drafts, recommendations, submissions and supporting research; • submissions made to the Minister and others on matters relating to therapeutic products regulation where the issue is controversial, or has significant legal, social, economic or international implications. Includes working papers; and • final versions of addresses and presentations made by the Minister or senior agency officers at major functions to promote the nation's therapeutic goods regulation system at significant public occasions.	
62397	Records documenting: • receipt, processing and evaluation of successful applications and conformity assessments from Australian and international manufacturers to import, export, or manufacture therapeutic goods, including biological and medical devices for experimental uses, or orphan drugs. Includes issuing approved statutory licences, permits and certificates; • testing for post market monitoring, compliance, investigations and	Retain for 120 years after action completed

THERAPEUTIC GOODS REGULATION

Class no	Description of records	Disposal action
	reviews, as well as market authorisation assessment for therapeutic goods. Includes test results, reports, recommendations etc. *[For registering approved listings, applications and conformity assessments in the Australian Therapeutic Goods Register, use THERAPEUTIC GOODS REGULATION – Class 62396]*	
62398	Records documenting: • unsuccessful applications and conformity assessments from Australian and international manufacturers to import, export, or manufacture therapeutic goods including biological and medical devices for experimental uses; and • unsuccessful applications to register therapeutic goods, including applications that are withdrawn, exempted, revoked or refused, and where clinical trials are approved but not proceeded with.	Destroy 70 years after action completed
62399	Records documenting: • routine operational administrative tasks supporting the core business; and • therapeutic goods regulation activities other than those covered in classes 62396 to 62398.	Destroy 7 years after action completed