EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Records Management

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1. Introduction and purpose

To comply with the legal, fiscal and institutional framework within which the EMA operates, all records produced or received by the Agency have to be systematically and efficiently managed throughout their entire *lifecycle*[1], i.e. from their *declaration* up to their *destruction* or permanent archiving. Such uniform record-keeping practices are fundamental to all EMA business units to:

- help fulfil corporate governance obligations such as transparency or good administrative behaviour[2];
- enhance business continuity;
- facilitate the access to corporate knowledge by enabling staff members to find with minimum delay and effort information required for their work; and
- achieve compliance with any applicable legal and regulatory framework, including Personal Data protection rules

This harmonisation in the management of records is based on the development and enforcement of an agency-wide Records Management (RM) policy, backbone of the EMA RM programme. This programme expects to:

- set and monitor policies and procedures for RM throughout the EMA;
- design, implement and maintain a *Business Classification Scheme* and *retention plan;*
- implement and manage *Record-Keeping Systems;*
- inform and train staff members about RM.

This RM policy complements "the EMEA Quality Policy"[3] and has been developed in accordance with the commonly recognised international standard for records management, "**ISO 15489-1:2016 Information and documentation - Records management**".

For the purpose of this policy, the following definition of record*s* applies:

"Any structured information[4] created or received by the EMA set aside by means of registration, protected against intentional or accidental alterations and retained as evidence and information of EMA activities in pursuance of legal obligations or in the transaction of business"

This policy aims to provide the basis for a consistent, sustainable and efficient records management programme by defining the method for the management of both paper and electronic records as a source of evidence and information. Together with the EMA-wide *Business Classification Scheme* and *retention plan*, this policy provides the overarching framework for any other corporate record-keeping practices detailed for example in Business Unit specific Standard Operating Procedures (SOPs).

[1] To facilitate the understanding of this document, RM-specific terms are written in *italic* and defined under Heading three "Definitions"
[2] Article 24 of "The European Code of Good Administration Behaviour", European Ombudsman (Refer also to Article 24 of EMA Code of Conduct)
[3] EMEA/230232/05 – The European Medicines Agency's integrated quality management system
[4] E.g. text, drawings, photos, messages written on paper or stored in digital form or as an audio, visual or audio visual recording

2. Scope

This policy applies to all staff (permanent and temporary employees, contractors, consultants and experts) who have access to EMA records, wherever these records are and whatever the format they are in.

This policy encompasses all records, whatever their format or medium (e.g. paper, digital, optical, audio, photographic) created or received by the EMA in the course of its operational or administrative activities.

EMA records shall be identified and retained according to the following values:

- **Business value:** records which serve the EMA as the official memory of past decisions, document decision-making processes and proves that the EMA fulfils the roles that it has been given e.g. marketing authorisation dossiers, guidelines, opinions, Commission decisions.
- **Legal and evidential value**: records which are required by legislation and which show that EMA is compliant with regulatory and statutory requirements, e.g. contracts, land transactions, protocol agreement.
- **Administrative value:** records which serve administrative purposes only, e.g. leave application forms, training request, performance evaluation.
- **Financial value:** documentary evidence of the way in which budget was obtained, planned, allocated, controlled and expended, e.g. mission request, bank statement, budget planning.
- **Research/historical value**: records which document the history or development of the Agency as well as scientific information on medicinal products received and handled by the EMA will need to be permanently preserved as they may be of use for future research.

This policy does not apply to *non-records*, which are documents used and kept for reference and information only or personal documents which were not created or received in pursuance of the Agency's institutional or legal obligations or in the transaction of business.

3. Definitions

TERM	DEFINITION	REFERENCE
Archives	1. Those records that are appraised as having continuing value. Traditionally the term has been used to describe records no longer required for current use which have been selected for permanent preservation. Also referred to as permanent records. 2. The place (building/room/storage area) where archival material is kept. 3. An organisation (or part of an organisation) responsible for appraising, acquiring, preserving and making available archival material.	Australian Standard AS 4390-1996, Part 1. Clause 4.5
Authenticity	A record must be what it claims to be.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Author	The individual, group or organization which produces a record.	

Business Classification Scheme (BCS)	Logical and systematic organization of files into cases or topics based on an analysis of the business functions and activities of the Agency. It provides a common and standard framework across EMA, allowing Business Divisions and Departments to share and classify the same information for interrelated functions.	
Capture	See *Declaration*	
Content	The intellectual substance of a document, including text, data, symbols, numerals, images, and sound.	
Context	The organizational, functional, and operational circumstances surrounding record's creation, receipt, storage, or use, and its relationship to other records.	
Creator	See *Author*	
Declaration	A deliberate action which results in the registration of a record into a record-keeping system. For certain business activities, this action may be designed into electronic systems so that the capture of records is concurrent with the creation of records.	Australian Standard AS 4390-1996, Part 1. Clause 4.6
Document	Any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to the policies, activities and decisions falling within the institution's sphere of responsibility.	Regulation (EC) 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents
Destruction	Process of eliminating or deleting records, beyond any possible reconstruction.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Integrity	A record must be complete and unaltered.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Lifecycle	A mapping of the stages in the life of a record from declaration to destruction or transfer to permanent archives	
Non-record	Documents used and kept for reference and information only or private and personal documents which were not created or received in pursuance of the Agency's institutional or legal obligations or in the transaction of business.	
Personal Data	Personal Data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who	Regulation (EU) 2018/1725[5] (EU DPR), Article 3(1)

[5] Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

	can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.	
Preservation	Processes and operations involved in ensuring the technical and intellectual survival of authentic records through time.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Record	Any structured information created or received by the EMA set aside by means of registration, protected against intentional or accidental alterations and retained as evidence and information of EMA activities in pursuance of legal obligations or in the transaction of business.	
Reliability	A record must be a full and accurate representation of the business transactions, activities, or facts to which it attests.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Record-keeping system (RKS)	Information systems which capture, maintain and provide access to records through time.	ISO 15489-1:2001 Information and Documentation - Records Management - Part 1: General
Retention plan (or retention list)	Document describing the minimum periods for retaining records and files according to their legal, business and accountability requirements and authorizing on a continuing basis and after the lapse of specified retention periods the destruction of those records and files that have no further (archival) value. The retention plan is based on the assessment of the business, legal administrative, financial and historical value of records and files.	
Structure	The manner in which elements are organized, interrelated, and displayed.	

Acronyms:

DREAM: Document, Records and Electronic Archives Management System

RM: Records management

SOP: Standard operating procedure

I-BD-DIL: Document and Information Lifecycle Service; Business Data Department, Information Management Division

FSS: Facilities Support Service

4. Policy statement

4.1 Legal and regulatory framework

As a European Institution, the EMA has a number of legal requirements for implementing and keeping adequate records of its functions and activities:

- Regulation (EC) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities applicable to EMA budget;
- Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data;
- Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents;
- Article 24 of "The European Code of Good Administrative Behaviour", European Ombudsman (Refer also to Article 24 of EMA Code of Conduct) which sets out specific requirements on the creation and management of records;
- Directive 2001/82/EC on the Community code relating to veterinary medicinal products;
- Directive 2001/83/EC on the Community code relating to medicinal products for human use; and
- Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and the subsequent legislation where keeping records could prove that the EMA fulfils the roles that it has been given.
- Council Regulation (EU) 2015/496 of 17 March 2015 amending Regulation (EEC, Euratom) No 354/83 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence
- Regulation (EEC, EURATOM) No 354/83 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community, and amended by Council Regulation (EC, EURATOM) No 1700/2003
- Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (hereinafter as 'EU DPR')

EMA is committed to developing and maintaining *record-keeping systems* that *capture* and maintain records with appropriate evidential characteristics in accordance with the requirements of this legal and regulatory framework.

4.2 Roles and Responsibilities

All records created by staff members, experts or consultants carrying out EMA business-related activities are the property of the EMA and all records received are in the custody of the Agency. Both type of records are subject to the Agency overall control. They must therefore be maintained in a systematic manner, compliant with established records management practices.

The role of all staff across the EMA in regards to their specific RM responsibilities is as follows.

4.2.1 EMA Senior Management and Heads of Division

EMA Senior Management and Heads of Division have the overall responsibility to:

- endorse and approve this records management policy; and
- support its application throughout the organisation.

4.2.2 I-BD-DIL (Records manager)

I-BD-DIL shall:

- maintain records management policy and procedures, EMA *Business Classification Scheme* and *retention plan* and assist with the monitoring for their use in line with professional best practices;
- ensure appropriate training and communication on RM;
- promote and support compliance with the EMA RM policy; and
- give other Business Unit/Sector advice and guidance for better RM practices.

4.2.3 Heads of Departments

Heads of Departments shall:

- ensure that appropriate resources exist within their Department for fulfilling the responsibilities for managing records;
- ensure that their Department complies with the provisions of the policy and its associated procedures and RM tools; and
- ensure that their staff members are fully aware of their responsibilities under the policy.

4.2.4 Head of Services

Head of Services shall:

- ensure that, where SOPs exist to support a process, records that must be kept are identified in the SOPs in compliance with this policy;
- ensure that their staff is trained and follows good practices for the management and storage of records; and
- provide input and feedback to I-BD-DIL to update and maintain RM policy and procedures.

4.2.5 IT Services and Delivery

IT shall:

- support and assist in the implementation of the RM components associated with the existing document management systems ;
- ensure that electronic storage systems are compliant with RM policy and related requirements;

- identify electronic information systems soon to be outdated and take appropriate measures with regards to electronic archiving.
- ensure the long term preservation and accessibility of relevant electronic records (i.e. format conversion, potential migrations, preservation of metadata and audit trails etc.)

4.2.6 FSS - Facilities s Support Services (Archives services)

Archives services shall:

- promote and support compliance with the archival aspects of the RM policy for hard copy records;
- ensure off-site archived records originated or received in hard copy are managed, physically and electronically, in compliance with this policy.
- guarantee the off-site storage keeps adequate environmental conditions to ensure long term physical preservation of relevant stored materials. (i.e. ventilation; temperature; humidity; pests; fire and flooding control)
- manage the day-to-day retrieval, access and security of files stored in the off-site physical archives

4.2.7 All staff

All staff shall:

- distinguish records from non-records and personal documents in accordance with RM guidance available;
- *declare* and manage records they are responsible for;
- protect records in their custody from unauthorised access or improper use;
- ensure that relevant records in hard copy no longer needed for frequent reference are sent back to the Archives Service; and
- hand over all relevant records to his or her successor in a timely manner when transferring responsibility for any function, project, product, transaction or activity.

4.3 Principles governing Records Management

Records are created and kept by the EMA to document its business and administrative transactions (i.e. what was communicated or decided, or what action was taken). To ensure its *integrity*, *authenticity*, *reliability* and *accessibility,* a record is not a stand-alone but rather a compound object which should contain not only the document itself (or *content*) but also the metadata (or *context*) and the format (or *structure*). These three characteristics are required to allow the reconstruction of the activities and transactions the records supports.

4.3.1 Record-keeping systems

The management of EMA records is ensured through the use of trustworthy *record-keeping systems* designed to *capture*, maintain and retrieve records while ensuring their continued *integrity* with appropriate evidential characteristics.

A *record-keeping system* must be able to manage the following records management processes:

- the *declaration* of records;
- the storage of records;
- the protection of record *integrity* and *authenticity*;
- the security of records;
- the access to records; and
- the disposal of records in accordance with the *retention plan*.

4.3.2 Declaration and filing of records

Records shall be *declared* into the adequate *record-keeping system* whenever there is a need for the EMA to provide evidence of its institutional or legal obligations or in the transaction of its business.

To ensure that records are complete and accurate and the information they contain is reliable and authentic, records shall:

- contain clear information on their business *context* (e.g. metadata such as date, title, *author*, product information);
- be *declared* according to the business process they support and document (e.g. a specific procedure or a project) by the identified owner of the activity;
- be *declared* in their original format (e.g. the electronic version of an email is the official record while a printed copy is only a convenience copy);
- be *declared* in a format / medium compatible with standard office applications available at the EMA;
- be filed in corporate record-keeping systems managed and monitored by their respective application managers; and
- be grouped together with records that relate to the same business activity / transaction / project / product.

To ensure that records are formally *declared* and that they are maintained in a uniform and consistent approach across the Agency, an EMA-wide *Business Classification Scheme* exists and is available as part of the RM programme.

4.3.3 Records Management and Personal Data

The Records management policy shall support the compliance with Regulation (EU) 2018/1725 and help to protect personal data and the privacy of individuals. In particular, as regards to the management of records which contain personal data, it shall be ensured that they are not processed for any purpose other than for which they were originally collected or for archiving purposes in the public interest. The Personal Data contained in such records shall be accurate and where necessary kept up to date, erased or rectified.

Personal Data shall be kept for no longer than is necessary for the purposes for which they were originally collected or for archiving purposes in the public interest. For this reason, the retention period of records containing Personal Data should be set based on a careful evaluation of how long it is strictly necessary to retain the Personal Data in order to fulfil its purposes. Records containing Personal Data may be retained for a longer period without data protection restriction in case it is anonymised, i.e. kept in a form which no longer permits the identification of the concerned individuals.

To that end, any guidance provided by the Data Protection Officer will override retention periods established by the Records management policy, as personal data will be destroyed entirely or redacted from records to be preserved whenever recommended by the Data Protection Officer as to ensure compliance with the above mentioned legislation.

4.3.4 Retention and disposal[6]

Records shall only be retained for as long as they are needed to support EMA's business activities or legal obligations. They then shall be disposed of in accordance with European Regulatory environment, business and accountability requirements and the risk associated with keeping or disposing of records at any particular point in time.

To ensure in accordance with this policy that records are retained for as long as they are needed and that records authorized for disposal and destroyed safely and securely, records shall be disposed:

- according to a common *retention plan* which is maintained by each business unit under the coordination of I-BD-DIL and
- with the assurance that they are no longer required, no work is outstanding and no litigation, investigation or access request is current or pending and
- after written approval and authorization of the respective manager of the unit or sector responsible for the activity with a possibility to delegate this task.

4.3.5 Preservation

Further implementation measures depending on the records' format shall be developed and applied in order to guarantee the long-term (i.e. more than 15 years) or permanent preservation of records with long term or permanent value. Thus, hard copy records must be stored in a controlled environment with adequate temperature, humidity and fire control systems in place. Procedures for the preservation of electronic records must take account of the obsolescence of hardware, software, file format and media formats used for storage of electronic records and provide for alternate hardware, software, file format and media formats to which the records can be migrated. Those systems need also to guarantee the adequate preservation of records context and structure over time. The responsibility for identifying systems soon to become outdated rests with the application manager of the system. The decision whether to maintain the outdated system, or to adopt a new system and migrate data into it, is taken by IT together with I-BD-DIL. They will also collaborate to address any other measure necessary to guarantee complaint electronic archiving for relevant records.

4.3.6 Retrieval of records

To ensure that records can be easily identified and retrieved when required in an efficient and effective approach, records shall:

- be *captured*, filed and stored using a harmonized approach within the Agency *record-keeping system*. An inventory of records and their location shall exist to ensure a better management of EMA's information asset and support a better search and retrieval;
- be identified by a unique identifier;
- be classified accordingly to prevent risk of unauthorised access or misuse and

[6]The EMA records retention list, referenced under Heading three Related documents" provides more detailed info about EMA records retention periods

- be indexed and described by a combination of metadata.

4.3.7 Access to records

Access to EMA records shall be regulated. Restrictions on access are applied both -within the Agency and outside, i.e. to external third parties and the general public, and reflect the legal and other rights of the EMA, its stakeholders and any other counterparts that might be affected by its actions. Personal Data shall be treated in accordance with Regulation 2018/1725 and regularly deleted when not needed anymore (See Section 4.3.3 above).

To ensure that access to records and the disclosure of information they contain are systematic, considered and consistent, access to records shall:

- be granted to all staff members who need access to the information the records contain to carry out their duties;
- be compliant with EU regulations on public access to documents[7] and the protection of Personal Data[8]; and
- be closely monitored and documented for certain types of records that contain information requiring disclosure control for reasons of security, personal privacy, commercial confidentiality and legal liability.

5. Monitoring

Staff and system compliance with this records management policy must be regularly monitored. Following established audit procedures, monitoring activities should be carried out through ad-hoc or planned audit procedures.

6. Related documents

EMA corporate filing plan: Business classification scheme
EMA/506416/2012
https://docs.eudra.org/webtop/drl/objectId/090142b2829312d9

EMA retention list
EMA/750675/2013
https://docs.eudra.org/webtop/drl/objectId/090142b282b0ba49

Statement of Intent on e-recordkeeping
EMA/735254/2009
https://docs.eudra.org/webtop/drl/objectId/090142b28114111f

Document Classification Policy0081
EMA/174602/2016
https://docs.eudra.org/webtop/drl/objectId/090142b283739a7e

[7] EU Regulation 1049/2001 regarding Public Access to documents
[8] Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

7. Changes since last revision

Policy reissued without major changes. This policy is updated to reflect the Agency new organisational chart and to include references to the EMA Document Classification Policy and the amending Regulation(EU) 2015/496 of 17 March 2015 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence

Amsterdam, 10 July 2019

[Signature on file]

Guido Rasi
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