

Ministry for Health
Health Care Standards
Data Protection and Retention Policy

SCOPE

1. This Policy is aimed at regulating the retention, maintenance and disposal of documentation, both personal and other, within the Health Care Standards, as provided for in the terms of requirements emanating from legal provisions in such other acts as the Public Administration Act chapter 595 and directives emanating therefrom, and in accordance with the principles of data protection legislation, and the National Archives Act chapter 477.

BACKGROUND

2. The General Data Protection Regulation (GDPR) (EU) 2016/679 puts forward the principle that personal and sensitive personal data, should not be retained for periods that are longer than necessary. In this context, the Health Care Standards will be putting forward a retention policy for all records collected and processed, with the purpose of ensuring compliance to the Regulation and to ensure that no resources are utilised in the processing and archiving of data which is no longer of relevance.

OBJECTIVES

3. This policy aims to achieve the following objectives:
 - Regulate the retention and disposal of the various types of records within the Health Care Standards while adhering to the Data Protection principle that personal data should not be retained for a longer period than necessary; as per Article 5 (e) in the GDPR.
 - Dispose of unnecessary documentation that is no longer relevant and is taking up useful storage space: as per Article 17 of the GDPR.
 - Promote the digitisation of documentation as may be reasonably possible in order to minimize the use of storage space required to store documentation, as well as to promote a sustainable use of paper and printing consumables.

THE DATA SUBJECT RIGHTS

4. The data subject is entitled to know, free of charge, what type of information the Health Care Standards holds and processes about him/her and why, who has access to it, how it is held and kept up to date, for how long it is kept, and what the Unit is doing to comply with data protection legislation.

The GDPR establishes a formal procedure for dealing with data subject access requests. All data subjects have the right to access any personal information kept about them by the Health Care Standards, either on computer or in manual files. Requests for access to personal information by data subjects are to be made in writing using the [Request for Access to Personal data By Data Subjects](#), and

sent to the Data Protection Officer of the Health Care Standards. The data subject identification details such as ID number, name and surname have to be submitted with the request for access. In case we encounter identification difficulties, the data subject may be required to present an identification document.

ADMINISTRATION

5. Documentation is held and recorded by the administration/booking office at the Health Care Standards. This policy is therefore applicable to all such documentation. It will be the responsibility of the Superintendent of the Public Health within the Department for Health Regulation, and its next level supervisor, being the Director of the Health Care Standards Directorate to ensure that all provisions of this policy are adhered to.
6. All staff that create, maintain, process and store records mentioned hereunder are responsible to perceive and implement the instructions given in this policy.
7. The next level supervisor, being the Director of the Health Care Standards following appropriate consultation and direction, is authorized to modify this policy as deemed appropriate from time to time to ensure compliance with state laws.

DOCUMENTATION HELD WITHIN THE HEALTH CARE STANDARDS

8. As part of its operating requirements the Health Care Standards requests, keeps and maintains a wide range of documentation including personal data. The type of data that is being utilised by Health Care Standards may be listed as follows:
 - Nursing and Caring Staff
 - Personal Details of Licensees on databases
 - Inspection tool for homes
 - Inspection tool for Tattoo studios
 - Inspection tool for body piercing studios
 - Inspection tools for Mental Health Facilities
 - Inspection tools for Health Care Establishments
 - Inspection tools for Oncology Facility
 - Inspection tool for Maternity Suites
 - Inspection tools for Operating Theatres
 - Inspection tools Rehabilitation Facilities
 - Organ Donor Leaflets
 - Organ Donor record on online Organ Register
 - Applications for new licenses of Acupuncture, Body Piercing, Chiropody, Dental Clinics, Medical Diagnostic Laboratories, Physiotherapy, Private Medical Clinics, Tattooist, Semi-Permanent Make up, Xray Clinics and Guest Tattooists
 - Aide Memoire for the Inspection of Eye Tissue Centres
 - Aide Memoire for the Inspection of Assisted reproduction Centres
 - Tissue Activity Dossier (TAD)

- Tissue /Cell Authorisation Application Form
- Inspection reports for BTC Establishments
- Blood SAR and SAE reports
- Dependency levels of residents of regulated Homes
- Dependency Levels of residents of regulated Homes
- Routine Inspection Reports
- Hepatiti B surface antibody reports
- Reports on complaints

SECURITY OF DOCUMENTATION

9. Documentation is maintained in an accessible but secure location with adequate access provided to officials who have the clearance level to access the relevant documentation. In the case of documents with sensitive personal data with higher clearance levels, access control protocols are fully adhered to, ensure that only those that have the required security clearance have access to such documentation.
10. In the case of personal data, the GDPR also stipulates that only those required to process personal data should have access to personal records.
11. Personnel who are found to be in breach of these security protocols, and thus in breach of the GDPR, will be subject to disciplinary action as per Article 33 Clause (5) of the GDRP.

MANUAL VS ELECTRONIC RECORDS

12. The same retention period will apply for both electronic (if applicable) and manual data.

RETENTION PERIOD

13. The Retention schedule hereunder outlines the retention requirements for the various categories of documentation within the Health Care Standards:

Key	Unit /Depart.	Category	Record Type	Description	Retention Period	Remarks	Action to be taken by the National Archivist (When Retention Period Expires)
1	Department for Health Regulation	Health Care Standards Directorate	Nursing and Caring Staff lists	These are lists of the names of the nursing and caring staff in the health care establishments licensed by the Health Care Standards Directorate	Five (5) years	Required by law as a condition for the issuing of a licence for the health care establishment. The legislation is Article 98 of the Medical and Kindred Professions Act (CAP 31)	Not required for permanent preservation by the National Archives.
2	Department for Health Regulation	Health Care Standards Directorate	Personal Details of Licensees on databases	These contain personal details of the licensees of the health care establishments licensed by the Health Care Standards Directorate	Five (5) years	None	Not required for permanent preservation by the National Archives.
3	Department for Health Regulation	Health Care Standards Directorate	Inspection Tool for Tattoo Studios	These are the forms used during the inspection of tattoo studios	Five (5)years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanet preservation.
4	Department for Health Regulation	Health Care Standards Directorate	Inspection Tool for Body Piercing Studios	These are the forms used during the inspection of body piercing studios	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanet preservation.
5	Department for Health Regulation	Health Care Standards Directorate	Inspection Tool for Dental Clinics	These are the forms used during the inspection of dental clinics	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanet preservation.
6	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools for Mental Health Facilities	These are the forms used during the inspection of mental health facilities	Five (5)years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanet preservation.

7	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools for Health Care Establishments	This is the form used during the inspection of health care establishments	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
8	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools for Oncology Facility	This is the form used during the inspection of oncology facilities	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
9	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools for Maternity Suites	This is the form used during the inspection of maternity suites	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
10	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools for Operating Theatres	These are the forms used during the inspection of operating theatres	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
11	Department for Health Regulation	Health Care Standards Directorate	Inspection Tools Rehabilitation Facilities	These are the forms used during the inspection of rehabilitation facilities	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.

12	Department for Health Regulation	Health Care Standards Directorate	Organ Donor Leaflets	These are the paper application forms filled by Maltese citizens whereby they state there wish to become organ donors and fill their personal details as well as which organs they would wish to donate.	Ten (10) years	None	Not required for permanent preservation by the National Archives.
13	Department for Health Regulation	Health Care Standards Directorate	Organ Donor record on online Organ Donor Register	The personal and sensitive personal data inputted from the organ donor application forms is inputted into the online Organ Donor Register, which is synchronised to work with the CDB. These records are kept till the organ donor dies and his/her organs are harvested.	Indefinite (till reviewed)	The Organ Donor Register falls under the Human Organs, Tissues and Cell Donation Act (CAP 558)	To be kept indefinitely by the concerned office.
14	Department for Health Regulation	Health Care Standards Directorate	Applications for new licenses of Acupuncture, Body Piercing, Chiropody, Dental Clinics, Medical Diagnostic Laboratories, Physiotherapy, Private Medical Clinics, Tattooist, Semi-Permanent Make-up, Xray Clinics and Guest Tattooists	Application forms containing personal details of the licensees of the respective health care establishments	Ten (10) years after closure of licence.	These forms are kept in the licensee's file which are stored in locked cupboards by the licensing officer at the Health Care Standards Directorate even after the licensee ceases to operate Retention period starts from the licence expiry date.	Transfer to the National Archives for permanent preservation.
15	Department for Health Regulation	Health Care Standards Directorate	Aide Memoire for the Inspection of Blood Establishments	These are the forms used during the inspection of Blood Establishments	Thirty (30) years		A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
16	Department for Health Regulation	Health Care Standards Directorate	Aide Memoire for the Inspection of Eye Tissue Centres	These are the forms used during the inspection of Eye Tissue Centres	Thirty (30) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.

17	Department for Health Regulation	Health Care Standards Directorate	Aide Memoire for the Inspection of Assisted Reproduction Centres	These are the forms used during the inspection of Assisted Reproduction Centres	Thirty (30) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
18	Department for Health Regulation	Health Care Standards Directorate	Tissue Activity Dossier (TAD)	The Tissue Establishment Dossier (TED) is a document which is submitted together with a new application for licensing of a tissue establishment. It provides information about the entity, the personnel, equipment, procedures and processes to be undertaken at the establishment. The TED helps the inspectors to get a primary insight into the activities to be undertaken and is part of the documentation supporting an application for licensing.	Thirty (30) years	None	Transfer to the National Archives for permanent preservation.
19	Department for Health Regulation	Health Care Standards Directorate	Tissue/Cell Authorisation Application Form	This is the form which needs to be filled to open a new Tissue/Cell Establishment	Thirty (30) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
20	Department for Health Regulation	Health Care Standards Directorate	Inspection Reports of BTC Establishments	These are inspection reports of blood, tissues and cells establishments	Thirty (30) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.

21	Department for Health Regulation	Health Care Standards Directorate	Blood SAR and SAE reports	These are reports regarding Serious Adverse Reactions and Serious Adverse Events received from the National Blood Transfusion Services	Thirty (30) years	None	Transfer to the National Archives for permanent preservation.
22	Department for Health Regulation	Health Care Standards Directorate	Routine Inspection Reports	These are the yearly inspection reports of health care establishments licensed by the Health Care Standards Directorate	Five (5) years	None	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.
23	Department for Health Regulation	Health Care Standards Directorate	Hepatitis B surface antibody reports	These are results of blood hepatitis B surface antibodies of tattooists, body piercers, semi-permanent makeup artists, dentists and acupuncturists	Ten (10) years	None	Not required for permanent preservation by the National Archives.
24	Department for Health Regulation	Health Care Standards Directorate	Reports on Complaints	The reports on complaints received about healthcare establishments licensed by the Health Care Standards Directorate	Ten years (unless there is any open litigation)	Possibility of litigation	A random sample of five (5) % of the records from every year is to be retained and sent to the National Archives for permanent preservation.

IMPLEMENTATION OF THE RETENTION PERIOD

14. The implementation of the said retention periods shall come into force as from 28th February 2019 cover all data held at the Health Care Standards. The first step will be to dispose of old documents dating back, held within the premises according to procedure and timeframes listed in this policy. Every file destroyed shall be documented by the staff to keep a track record. Eventually officers responsible for data listed in the retention schedule will, following approval by the management team, dispose of such data according to the given timeframes.

CONCLUSION

15. This retention policy is intended towards achieving a good working balance between the retention of useful information and the disposal of data which is no longer required and is being unnecessarily archived. Data that needs to be destroyed will be disposed of in an efficient manner to ensure that such information will no longer be available within the Health Care Standards. Data Protection Controllers, Heads, and DPOs will be made aware of the noted retention periods and will instruct all relevant personnel to follow the indicated procedures accordingly.

It is to be noted that anonymised data do not fall within the parameters of this Retention Policy, since they do not constitute identifying personal data

The Data Protection Officer of the Health Care Standards may be contacted at:

Address: Health Care Standards Directorate,
Department for Health Regulation,
Level 1 Ex-OPD, St Luke's Hospital,
St Luke's Square,
Gwardamangia PTA 1010
E-mail: gdpr.hcs@gov.mt
Telephone: 25953323

The Information and Data Protection Commissioner

The Information and Data Protection Commissioner may be contacted at:
Level 2, Airways House,
High Street,
Sliema SLM 1549
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