

HEALTH INFORMATION AND QUALITY AUTHORITY

And

ENVIRONMENTAL PROTECTION AGENCY

DATA SHARING AGREEMENT

THIS AGREEMENT is made the 20 day of December 2017 (the commencement date)

1. BETWEEN:

1. The Environmental Protection Agency (the EPA) an independent public body established under the Environmental Protection Agency Act, 1992 and having its office at PO Box 3000, Johnstown Castle Estate, County Wexford, Y35 W821, Ireland
2. The Health Information and Quality Authority, (HIQA) a corporate body established under the Health Act 2007 having its head office at Unit 1301, City Gate, Mahon, Cork, Ireland

2. DEFINITIONS

The following definitions apply in this Agreement:

- "Act" means the Health Act 2007 (as amended)
- "Agreement" shall mean this data sharing agreement, including these definitions and its recitals and schedules, which is a free standing document that does not incorporate commercial business terms established by the parties under separate commercial agreements.
- "Commencement Date" has the meaning given to it at the beginning of the Agreement
- "Data Controller" shall have the meaning as set out in the DPA.
- "Data Processor" shall have the meaning as set out in the DPA.

"DPA" or	
"Data Protection	
Act"	means the Data Protection Acts 1988 and 2003 (as amended)
"Data Security Breach"	shall mean a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to shared personal data
"Data Subject"	shall have the meaning as set out in the DPA.
"Directive"	means Council Directive 2013/59/EURATOM of 5 December 2013 as affected by Corrigendum to Council Directive 2013/59/EURATOM
"Equipment"	means any medical device which emits ionising radiation for the purpose of the medical diagnosis or treatment of a patient
"EU General	
Data Protection	
Regulation"	means General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)
"Licence"	means permission granted by the EPA under the Radiological Protection Act, 1991 (as amended) to carry out a practice in accordance with specific conditions
"Personal Data"	shall have the meaning as set out in the DPA.
"Privacy and Data	
Protection Requirements"	means the Data Protection Acts 1988 and 2003 (as amended), the EU Data Protection Directive 95/46/EC, the ePrivacy Regulations 2011 (SI336/2011), the ePrivacy Directive 2002/58/EC and all applicable laws and regulations relating to the processing of personal data and privacy, including where applicable the guidance and codes of practice issued by the Data Protection Commissioner
"Registration"	means permission granted by the EPA under the Radiological Protection Act, 1991 (as amended) through a simplified authorisation procedure, to carry out a practice in accordance with conditions laid down in the legislation or specified by the Agency for this type or class of practice
"Regulations"	means the EU (Basic Safety Standards for Protection Against Dangers from Medical Exposure to Ionising Radiation) Regulations 2018 and the Radiological Protection Act, 1991 (Ionising Radiation) Regulations, 2018

“Technical and Organisational Measures”

means those measures aimed at protecting personal data against accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing

“Undertaking”

shall have the meaning as set out in the EU (Basic Safety Standards for Protection Against Dangers from Medical Exposure to Ionising Radiation) Regulations 2018.

3. PURPOSE

This agreement sets out the framework for the sharing of Data between the parties as Data Controllers. It defines the principles and procedures that the parties shall adhere to and the responsibilities the parties owe each other.

4. SCOPE

- 4.1 In consideration of sharing data with each other the parties agree that they will comply fully with their obligations as "data controllers" under the DPA, the EU GDPR and any guidance Issued by the Data Protection Commissioner.
- 4.2 The parties agree to co-operate in respect of the sharing of data in compliance with their proposed respective statutory functions under the Regulations.
- 4.3 The parties consider this data sharing agreement necessary In contemplation of and In furtherance to the exercise of the statutory powers and functions that will be conferred on the parties for the purpose of national compliance with the Directive and pursuant to their respective functions under the EU (Basic Safety Standards for Protection Against Dangers from Medical Exposure to Ionising Radiation) Regulations and the Radiological Protection Act, 1991 (Ionising Radiation) Regulations, 2018, which are due to be commenced on 6thFebruary 2018. The exchange of data Is essential for HIQA to Identify undertakings responsible for emission of ionising radiation in the medical screening, diagnosis or treatment of patients and to ensure ongoing national Implementation of the Directive by the parties, acting as competent authorities under the regulations. The aim of the agreement is for the parties to share regulatory solicited and unsolicited information relevant to the exercise of their respective statutory functions as competent authorities under the Regulations.
- 4.4 The parties agree that the data sharing agreement will serve to benefit the public Interest by way of regulation to ensure the provision of basic safety standards for protection against the dangers arising from exposure to ionising radiation.
- 4.5 The parties agree to only share data for the purpose set out at 4.3.
- 4.6 The parties shall ensure compliance with applicable national data protection laws at all times during the terms of the agreement.
- 4.7 The parties shall ensure that this agreement remains fit for purpose, accurate and up to date and it will be reviewed as is required by the parties. Such a review may be required following the adoption of the EU General Data Protection Regulation and the EU Basic Safety Standards Directive for the protection against dangers from exposure to ionising radiation) 2014. Any amendments to the agreement shall be signed by the parties.
- 4.8 The parties agree to comply with their responsibilities outlined in Schedule 1 of this Agreement with regard to the sharing of personal data. The parties agree that Schedule 1 of this Agreement shall form part of this Agreement and shall have the effect as if it was set out In full in the body of this Agreement.

- 4.9 The parties agree that in addition to the initial data transfer from the EPA to HIQA, all future transfers of data between the parties will comply with the parties policies and procedures for data transfer. Both the EPA and HIQA will install technical and organisational measures and shall be responsible for the secure and appropriate storage of all data records in their own computing infrastructures. In this regard, both the EPA and HIQA agree to comply with relevant requirements in relation to the processing, keeping, use and disclosure of data under the DPA and in particular to keep such Information confidential and to take appropriate security measures against unauthorised access to, or unauthorised alteration, disclosure or destruction of data.
- 4.10 The parties shall appoint a single point of contact (SPoC) who will work together to reach an agreement with regards to any issues arising from the data sharing and to actively improve the effectiveness of the data sharing agreement. The points of contact for each of the parties are;

EPASPoC

David Pollard

Programme Manager (Radiation Protection Regulation)

Office of Radiation Protection & Environmental Monitoring

EPA, 3 Clonskeagh Square, Dublin 14

Email: d.pollard@epa.ie

Phone: 01 2066926

HIQASPoC

Sean Egan

Head of Healthcare Regulation

Regulation Directorate

HIQA Unit 1301, City Gate, Mahon, Cork,

Email: segan@hiqa.ie

Phone: 021 2409336

5. FAIR AND LAWFUL PROCESSING

- 5.1 The parties shall ensure that they process the data fairly and lawfully in accordance with and during the term of the agreement.
- 5.2 The parties will only request data that is adequate and not excessive to the purpose of the agreement as set out in Section 4.3.
- 5.4 Data will be retained by the parties for no longer than is necessary for the purpose of this agreement as referred to in Section 4.3.
- 5.5 The parties agree that any third party processing will be covered by contract appointing the third party as Data Processor.
- 5.6 The parties agree to implement appropriate technical and organisational measures to protect against unauthorised access, accidental loss, destruction, damage, alteration or disclosure of data.

6. DATA QUALITY

- 6.1 The parties shall be responsible for the quality and accuracy of the data they share with the other party.
- 6.2 The EPA shall ensure that before the commencement date, all data to be shared with HIQA is accurate and up to date.
- 6.3 The parties agree that any data discovered to be inaccurate or inadequate for the specified purpose as defined in Section 4.3 will be brought to the notice of the party that supplied the data. The party that supplied the data shall be responsible for correcting the data and notifying the other party of the correction.

7. DESCRIPTION OF DATA TO BE TRANSFERRED

- 7.1 The EPA agrees to supply HIQA with a list of all undertakings registered or licensed by the EPA.
- 7.2 The EPA agrees to supply HIQA with the following data, subject but not limited to each undertaking;
 - a) Name of undertaking
 - b) Description of organisation/entity type of undertaking
 - c) Company registration details of undertaking where applicable
 - d) Contact details including phone and email details for undertaking

- e) Name of person in undertaking with overall responsibility for management of equipment
 - f) Purpose for which licence or registration has issued by EPA to undertaking
 - g) Type and specification of equipment held by undertaking for which licence or registration has issued
 - h) Location of equipment held by undertaking for which licence or registration has issued
 - i) Location of operation of equipment held by undertaking for which licence or registration has issued
 - j) Any other relevant information held by the EPA in relation to the undertaking
- 7.3 The parties agree to share data they deem relevant and necessary for the discharge of their statutory functions including but not limited to the data specified in Section 7.1 of this agreement.

8. PROCEDURES FOR TRANSFER OF DATA

- 8.1 The parties agree the following procedures for initial data transfer;

The EPA will create a data file containing the information relating to all licensee records for ionising radiation. The data contained within the file will be encrypted.

The data file will be transferred to HIQA.

The data transfer will be implemented by means of an encrypted file transfer protocol over a secure and robust connection.

Acknowledgement of receipt of the data file will be provided by HIQA.

- 8.2 The parties agree that in addition to the initial data transfer from the EPA to HIQA, all future transfers of data between the parties will comply with the parties' policies and procedures for data transfer, and will ensure secure transfer of data between organisations. Both the EPA and HIQA will install technical and organisational measures and shall be responsible for the secure and appropriate storage of all data records in their own computing infrastructures.
- 8.3 All data transferred under this agreement, personal or otherwise will be used solely for the purpose and to the extent specified in this agreement.

9. DATA SUBJECT RIGHTS

- 9.1 Data subjects have the right to obtain certain Information about the processing of their personal data through a subject access request.
- 9.2 The parties agree to provide reasonable assistance as is necessary to each other to enable them to comply with the subject access request and respond to any other queries or complaints from data subjects.
- 9.3 If one party to this Agreement receives a data subject access request, and personal data is subsequently identified as having originated from the other party, It will be the responsibility of the receiving party to contact the party that supplied the data to determine whether the supplier wishes to claim an exception under the provisions of either the Data Protection Acts 1988 & 2003 or Freedom of Information Acts 1997, 2003 & 2014.

10. RESTRICTION ON USE OF DATA

- 10.1 All data shared by the parties to this Agreement, personal or otherwise, must only be used for the reason(s) specified in the Agreement at the time of disclosure(s) and as set out in Section 4 of this Agreement. The data must not be used for any other purpose without the permission of the party who supplied the data, unless an exemption applies within the DPA or the data is required to be provided under the terms of the Freedom of Information Acts 1997, 2003 & 2014 or under the instructions of a court of law.

11. LEGAL BASIS FOR DATA SHARING

- 11.1 All data, including personal data, shared under this Agreement is done so including but not limited to the following legislation;

The Health Act 2007 as amended

The Radiological Protection Act, 1991 as amended

EU (Basic Safety Standards for Protection Against Dangers from Medical Exposure to Ionising Radiation) Regulations 2018

The Radiological Protection Act, 1991 (Ionising Radiation) Regulations, 2018.

Data Protection Acts 1988 and 2003 (as amended), the EU Data Protection Directive 95/46/EC, the ePrivacy Regulations 2011 (SI336/2011), the ePrivacy Directive 2002/58/EC

General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679)

12. DATA SECURITY BREACHES

- 12.1 The parties shall have in place their own guidance and policy that must be followed in the event of a data security breach.
- 12.2 The parties shall appoint a single point of contact (SPoC) for data security breach who shall;
- a) maintain records in relation to data protection requests, decisions made and information exchanged
 - b) maintain records of any data breach
 - c) notify each other of the breach within 24 hours of its discovery
 - d) inform the Data Protection Commissioners Office when a breach has occurred

The points of contact for each of the parties are:

EPA SPoC

Bernard Browne

Data Protection Officer

EPA

PO Box 3000, Johnstown Castle Estate, County Wexford, Y35 W821

Email: b.browne@epa.ie

HIQA SPoC

Brian Ahern

Data Protection Officer

HIQA Unit 1301, City Gate, Mahon, Cork,

Email: bahern@hiqa.ie

- 12.3 The parties agree to notify any potential or actual loss of data to each SPoC as soon as possible to enable the parties to consider what action is required to resolve the issue in accordance with the data protection laws and guidance.
- 12.4 The parties agree to provide reasonable assistance as is necessary to each other to facilitate the handling of any data security breach in an expeditious and compliant manner.

13. INDEMNITY

- 13.1 The parties to this Agreement, agree to indemnify each other, against any action arising out of their failure to act within the terms of this Agreement, or in relation to wrongful or negligent disclosure of data generally relating to actions taken in the context of this Agreement.

14. GOVERNING LAW

- 14.1 This Agreement will be governed by and construed in accordance with the laws of Ireland, and the parties submit to the exclusive jurisdiction of the Irish courts for all purposes connected with this Agreement, including the enforcement of any award or judgement made under or in connection with it.

15. SEVERANCE AND UNENFORCEABILITY

- 15.1 If any provision, or part thereof, of this agreement shall be, or is found by any authority, administrative body or court of competent jurisdiction to be, invalid, unenforceable or illegal, such invalidity, unenforceability or illegality shall not affect the other provisions, or parts thereof of this Agreement, and of which shall remain in full force and effect.
- 15.2 If any invalid, unenforceable or illegal provision, or part thereof, would be valid, enforceable or legal if some part were deleted, the provision, or part thereof, will apply with whatever modification is necessary to give effect to the intention of the parties as appears from the terms of this agreement.

16. TERMINATION

- 16.1 This agreement shall remain in force from the commencement date unless it is superseded by the provisions of a further written agreement concluded between the parties or is terminated by either party by notice in writing of one month to the other party.
- 16.2 Where this agreement is terminated by either party, the parties shall ensure that any shared personal data is returned or destroyed in a secure manner.

SCHEDULE 1

RESPONSIBILITIES OF PARTIES WHEN SHARING PERSONAL DATA

In consideration of the parties sharing personal data with each other, the parties agree to;

1. The parties shall request data that is adequate and not excessive to the purpose of this agreement as set out in Section 4.3.
2. The parties shall ensure that they process the shared personal data fairly and lawfully in accordance with and during the term of the agreement.
3. The data will be retained by the parties for no longer than is necessary in accordance with the discharge of their respective statutory functions.
4. The parties agree to keep the personal data secure and confidential.
5. To ensure personal data is adequately safeguarded, the parties agree that any third party processing will be covered by contract appointing the third party as Data Processor and the contract will stipulate the following;
 - The conditions under which the data may be processed including but not limited to compliance of the Data Processor with the DPA, the EU GDPR and any guidance issued by the Data Protection Commissioner
 - The minimum security measures that the data processor must have in place
 - A provision to enable the Data Controller to ensure that the Data Processor is compliant with the terms of the contract in relation to access and security of data
6. The parties will ensure that the security of all personal data stored on all fixed and mobile devices, including desktop computers, servers and mobile computer devices (i.e. laptops, notes, tablets, personal data assistants, Blackberry enabled devices, iPads, iPhones and other smart type devices etc) and removal storage devices (i.e. CD, DVD, portable hard drives, USB memory keys, Diskettes, ZIP disks, Magnetic tapes etc).
7. The parties will ensure that non-electronic personal data is managed and stored securely.
8. The parties agree to implement appropriate technical and organisational measures to protect against unauthorised access, accidental loss, destruction, damage, alteration or disclosure of personal data.
9. The parties will ensure that all relevant staff are appropriately trained to handle and process shared personal data in accordance with the technical and organisational measures in their own computing infrastructures. The parties shall

ensure that all relevant staff are aware and act in compliance with the Agreement and this will be supported by the implementation of appropriate policies and procedures.

10. The parties agree not to transfer any personal data outside the European Economic Area (EEA) except with the prior written consent of the party who supplied the personal data
11. The parties will ensure that all personal data (irrespective of the format that the data is held, i.e. paper, electronic or otherwise) that is no longer necessary, is deleted and disposed of in a secure manner.
12. In the interests of transparency and so that citizens are aware of the potential for their personal data covered by this agreement to be shared, the agreement will be published on the websites of the parties as soon as possible after the signing of same.
13. The parties agree to comply with the provisions of Section 12 of this Agreement in the event of any accidental or unauthorised data security breach.
14. The parties agree to comply with the provisions of Section 9 of this Agreement in the event of a data subject request.
15. Where this agreement is terminated by either party, the parties shall ensure that that any shared personal data is returned or destroyed in a secure manner.
16. Where the agreement is terminated, the confidentiality of personal data shared between the EPA and HIQA is to be maintained in perpetuity.

IN WITNESS where of this Agreement has been entered into the day and year first herein written.

SIGNED on behalf of the
Health Information and Quality Authority



Signature

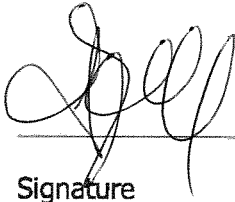
SEAN EGAN

Name (Printed)

HEAD OF HEALTHCARE
REGULATION

Title

In the presence of



Signature

Aoife McCann

Name (Printed)

SENIOR LEGAL ADVISOR

Title

SIGNED on behalf of the
Environmental Protection Agency



Signature

DAVID POLLARD

Name (Printed)

PROGRAMME MANAGER

Title

In the presence of



Signature

NOELEEN CUNNINGHAM

Name (Printed)

INSPECTOR

Title

Date: 20 DEC 2017

Date: 20-12-17

