

# Health Information and Quality Authority (HIQA)

AND

## The Environmental Protection Agency

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### DATA SHARING AGREEMENT

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THIS AGREEMENT is made on the 8<sup>th</sup> day of October 2021 (the commencement date)

#### 1. BETWEEN

1. 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.

And

2. 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.

(the Parties)

#### 2. DEFINITIONS

The following definitions apply in this Agreement:

“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 this Agreement.
“Data Controller”	shall have the meaning as set out in Data Protection Law.
“Data Processor”	shall have the meaning as set out in Data Protection Law.

Data	shall mean Personal Data and or/Special Categories of Personal Data as set out in Data Protection Law
"DPA" or	
"Data Protection Act"	means the Data Protection Act 2018 (as amended).
"Data Protection Law"	all applicable laws and regulations relating to the processing of Data, including, in particular, the GDPR, the DPA and any statutory instruments, rules, orders or regulations made thereunder as from time to time amended, extended, re-enacted, replaced or consolidated (whether before, or after the date of this Agreement).
"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 attributed to it in Data Protection Law.
"Directive"	means European Union Basic Safety Standards (BSS) Council Directive (Council Directive 2013/59/EURATOM)
"GDPR"	means General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679).
"Ionising Radiation	
Regulations "	means the Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019 (SI No 30 2019)
"Law Enforcement	
Directive"	means Directive (EU) 2016/680 of the European Parliament and of the Council
"Personal Data"	shall have the meaning as set out in the Data Protection Law.
"Privacy and Data	
Protection Requirements"	means the GDPR, DPA, 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.
"Regulations"	Ionising Radiation Regulations and Medical Exposure Regulations collectively

“Medical Exposure

Regulations”

means the EU (Basic Safety Standards for Protection Against Dangers from Medical Exposure to Ionising Radiation) Regulations 2018 and the EU (Basic Safety Standards for Protection Against Dangers from Medical Exposures to Ionising Radiation) (Amendment)(No.2) Regulations 2019

“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 process.

### **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 as Data Controllers 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 Data Protection Law 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 respective functions under the Regulations.
- 4.3 The Parties consider this Agreement is necessary to facilitate the sharing of Data and other information pursuant to the Memorandum of Understanding (MOU) entered into by the Parties on 3<sup>rd</sup> February 2020. The MOU is designed to provide a mechanism to assist cooperation between the Parties to ensure maximum effectiveness and efficiency when carrying out their respective functions in the best interests of the public. This Agreement is necessary in furtherance of the powers and functions conferred on the Parties for the purpose of national compliance with the Directive and pursuant to their respective functions under the Regulations. Section 8(1)(n) of the Health Act 2007 (as amended) provides HIQA with the function ‘to exercise such powers and perform such functions of the State and the competent authority under Council Directive 2013/59/Euratom of 5 December 2013 as are conferred on the Authority by SI No. 256 of 2018’. The purpose of this Agreement is for the Parties to share Data and other information relevant to the exercise of their respective functions as competent authorities under the Regulations.
- 4.4 The Parties agree that this Agreement will serve to benefit the public interest by way of regulation to ensure the provision of basic safety standards for the protection of

service users, staff and members of the public against dangers arising from exposure to ionising radiation.

- 4.5 The Parties agree to only share Data for the purpose set out in Section 4.3.
- 4.6 The Parties shall ensure compliance with applicable Data Protection Laws at all times during the term of this 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 amendments to national Data Protection Law and future guidance issued by the Data Protection Commission or any amendments to other relevant legislation or regulations. Any amendments to this 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 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 all the required Data transfers between the Parties will comply with the Parties' policies and procedures for Data transfer. Both Parties will install technical and organisational measures and shall be responsible for the secure and appropriate storage of all Data records in their own computing and manual filing infrastructures. In this regard, both parties to this Agreement agree to comply with relevant requirements in relation to the processing, keeping, use and disclosure of Data under Data Protection Law 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 each 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 this Agreement. The points of contact for each of the Parties are:

**HIQA SPoC**

The person holding the position of Regional Manager (Ionising Radiation)

Currently:

John Tuffy

Georges Court

Georges Lane

Smithfield

Dublin 7

01-8147400

jtuffy@hiqa.ie

**EPA SPoC**

Collette O Connor

Manager Ionising Radiation Regulation

Environmental Protection Agency

McCumiskey House

Richview

Dublin 14

**5. FAIR, LAWFUL AND TRANSPARENT PROCESSING**

- 5.1 The Parties shall ensure that they process the Data fairly and lawfully in accordance with and during the term of this Agreement.
- 5.2 The Parties will only request Data that is adequate and not excessive to the purpose of this Agreement as set out in Section 4.3.
- 5.3 Data will be retained by the Parties for no longer than is necessary for the purpose of this Agreement as set out in Section 4.3.
- 5.4 The Parties agree that any third party Data processing shall be governed by contract setting out the subject matter and duration of processing, the nature and purpose of the processing, the type of Data and categories of Data Subjects and the obligations and rights of the Data Controller. The Parties will ensure that any Data processing contract entered into shall meet the requirements of Article 28 of the GDPR.
- 5.5 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 Each party shall be responsible for the quality and accuracy of the Data they share with the other party.
- 6.2 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 details of licensees and or registered persons authorised by the EPA in accordance with the Ionising Radiation Regulations to undertake medical exposure practices. This information shall include the following:

- a) Name of the undertaking
- b) Description of organisation and entity type of undertaking
- c) Company registration details of undertaking (where applicable)
- d) Undertaking reference number
- e) Contact details for the undertaking, including phone, address and email details
- f) Name and contact details of person in undertaking with overall responsibility for management of medical radiological equipment
- g) Practices covered by the licence or registration
- h) Type and specification of equipment held by undertaking for which a licence has issued
- i) Location of medical radiological equipment held by an undertaking for which a licence or registration has issued
- j) Location at which the operation of medical radiological equipment, held by an undertaking for which a licence or registration has issued, takes place.
- k) Any other information held by the EPA relevant to HIQA in carrying out its functions pursuant to the Medical Exposure Regulations.

**7.2** HIQA agrees to supply the EPA with details of undertakings within the meaning of the Medical Exposure Regulations. This information shall include:

- a) Name of undertaking
- b) Description of organisation/entity type of undertaking
- c) Company registration details of undertaking where applicable
- d) Organisational service value reference number
- e) Contact details including phone and email details for undertaking
- f) Details of locations where medical radiological practices are to be carried out under the control of the undertaking
- g) Radiological service types provided at the locations where medical radiological practices are carried out under the control of the undertaking.
- h) Name and contact details of person in undertaking with overall responsibility for management at each location.
- i) Any other information held by the HIQA relevant to the EPA in carrying out its functions pursuant to the Ionising Radiation Regulations.

**7.3** The Parties agree to share information or Data with each other relating to radiation incidents which may also be relevant to the other party in carrying out its functions pursuant to the Regulations. Any information or Data shared shall be in accordance with the parties obligations under Data Protection Law..

- 7.4** The Parties agree to share information or Data, as necessary, to aid in the justification of a class or type of practice under their respective Regulations and regulatory remit.
- 7.5** The Parties agree to share Data with each other where it is necessary for the performance of their respective functions pursuant to the Regulations. This includes, but is not limited to the following circumstances:
- the EPA withdraws or attaches a condition to a licence or registration under the Ionising Radiation Regulations;
  - the EPA issues an enforcement notice under the Ionising Radiation Regulations;
  - HIQA issues a compliance notice or prohibition order against an undertaking or person under the Medical Exposure Regulations;
  - HIQA and/or the EPA take enforcement proceedings against an undertaking or a person in relation to an offence under the Regulations.
- 7.6** The Parties agree on the cross-referral of concerns which one party believes falls within the remit of the other (or both). This includes but is not limited to circumstances where either party through its statutory investigation, monitoring and registration processes becomes aware of concerns relating to the provision of a service that may lead to a risk to the safety of service users or staff and members of the public (as appropriate) from exposure to ionising radiation. Any information or Data shared shall be in accordance with the parties obligations under Data Protection Law.
- 7.7** The Parties agree to share relevant information, records and Data to facilitate in the calculation of population dose for medical exposures and other statistics as required under the Regulations.
- 7.8** The Parties agree to share information relating to the scheduling of fieldwork activities, when requested by the other party and where practicable to do.

## **8. PROCEDURES FOR TRANSFER OF DATA**

- 8.1** The Parties agree the following procedures for the transfer to Data:

The disclosing party will create a data file containing the Data to be transferred. The Data contained within the file will be encrypted.

The data file will be transferred to the other party.

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

Acknowledgment of receipt of the Data file will be provided by the party in receipt of the Data.

- 8.2** The Parties agree that all Data transfers between the Parties will comply with the Parties' policies and procedures for Data transfer, and will ensure secure transfer of

Data between the Parties. Both Parties will install appropriate technical and organisational measures and shall be responsible for the secure and appropriate storage of all Data records in their own computing and manual filing infrastructures.

8.3 All Data and any other information transferred under this Agreement 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 following rights under data protection law:

- right of access (Article 15 GDPR);
- right to rectification (Article 16 GDPR);
- right to erasure (Article 17 and 19 GDPR)
- right to restriction of processing (Article 18 GDPR);
- right to data portability (Article 20 GDPR) and the right to complain to the relevant data protection authority if they believe that the Data Controller has not handled their Data in accordance with data protection requirements.

9.2 The Parties agree to provide reasonable assistance as is necessary to each other to enable them to comply with data subject rights requests and respond to any other queries or complaints from data subjects.

9.3 Where Data is being processed for law enforcement purposes, the rights of Data Subjects under the Data Protection Act are as follows:

- right to information (Section 90 DPA)
- right of access (Section 91 DPA)
- right or erasure and restriction of processing (Section 92 DPA)

## **10. RESTRICTION ON USE OF DATA**

10.1 All Data and any other information shared by the Parties must only be used for the reasons specified in this Agreement at the time of disclosure 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 or information, unless an exemption applies within Data Protection Law or the Data is required to be provided under the terms of the Freedom of Information Act 2014 or under the instructions of a court of law.

## **11. LEGAL BASIS FOR DATA SHARING**

11.1 Data shared under this Agreement is done so on the basis that it is necessary for the performance of a task carried out in the public interest or necessary for the exercise of official authority vested in the Data Controllers as permitted by Article 6(1)(e) GDPR and Section 38 of the DPA.



- 11.2 Article 9(2)(i) GDPR and Section 53 of the DPA also permits the processing of healthcare Data which is "special category data" under the GDPR, where necessary for public interest reasons in the area of public health, which includes ensuring high standards of quality and safety in healthcare.
- 11.3 Data may also be shared by the Parties under this Agreement on the basis of Article 6(1)(d) where necessary and proportionate to protect the vital interests, or health and safety of persons.
- 11.4 Data may also be shared by the Parties under this Agreement on the basis of Article 6(1) (c) where processing is necessary for compliance with a legal obligation to which the Data Controller is subject.
- 11.5 Regulation 3(4) of the Medical Exposure Regulations enables HIQA to share Data with the EPA on the following basis: 'The Authority shall co-operate with the EPA in the carrying out of the Agency's functions under the Directive, in particular in relation to the withdrawal of authorisation, registration or licenses as appropriate, and may share data with the Agency for that purpose'.
- 11.6 The purpose of this processing is to enable the Parties to perform their functions under the following:
- Ionising Radiation Regulations
  - Medical Exposure Regulations
  - The Health Act 2007 (as amended)
  - Radiological Protection Act 1991 (as amended)
  - Section 52 of the Environmental Protection Agency Act 1992 (as amended)
- 11.7 Certain Data shared pursuant to this Agreement may fall to be considered under Part 5 of the Data Protection Act, which transposes the Law Enforcement Directive into Irish Law. In this instance, the processing of Data for law enforcement purposes is lawful on the basis that it is required for the performance of a function of HIQA, and the function has a legal basis in law namely the Health Act 2007(as amended) and the Medical Exposure Regulations. When processing Data for law enforcement purposes, the Data Controller shall ensure it is compliant with the relevant provisions of Part 5 of the Data Protection Act.

## **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 Breaches 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 Commission when a breach has occurred

The points of contact for each of the Parties are:

**HIQA SPoC**

The person holding the position of Data Protection Officer

Currently: Lydia Buckley

Unit 1301, City Gate, Mahon, Cork, Ireland.

021-4547722/0858709023

[dpo@hiqa.ie](mailto:dpo@hiqa.ie)

**EPA (SPoC)**

Currently: Tom O' Reilly

Data Protection Officer

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

053-9160630

[dpo@epa.ie](mailto:dpo@epa.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. LIABILITY**

13.1 Each Party shall be responsible and liable for its own acts and omissions and there shall be no joint or several liability between the parties.

To the extent that either Party has any liability to the other Party in contract, tort (including negligence), or otherwise under or in connection with this Agreement, including any liability for breach of warranty, that Party's liability shall be limited in accordance with the following provisions of this Clause.

- (a) In no circumstances shall either Party be liable for any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by the other Party that is

- (i) of an indirect, special or consequential nature; or (ii) any loss of profits, revenue, business opportunity or goodwill.
- (b) Nothing in this Agreement excludes or limits any Party's liability for death or personal injury caused by that Party's negligence, for fraud or fraudulent misrepresentation or for any other liability to the extent it cannot be excluded or limited under applicable law.

#### **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.

#### **17. EXECUTION**

- 17.1 This DSA may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. The Parties have the option to execute the Agreement by means of a simple electronic signature which shall be considered as an original signature and shall have the same validity, enforceability and permissibility as the original signature for the purpose of this Agreement.

## **SCHEDULE 1**

### **RESPONSIBILITIES OF PARTIES WHEN SHARING DATA**

In consideration of the Parties sharing Data with each other, the Parties agree as follows:

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 Data fairly and lawfully in accordance with and during the term of this Agreement.
3. The Data will be retained by the Parties for no longer than is necessary.
4. The Parties agree to keep the Data secure and confidential.
5. To ensure Data is adequately safeguarded, the Parties agree that any third party processing will be governed by a contract appointing the third party as Data Processor and shall be in accordance with Section 5.4 of this Agreement and Article 28 of the GDPR. Any third party processing contract will stipulate the following:
  - The conditions under which Data may be processed including but not limited to compliance of the Data Processor with Data Protection Law and any guidance issued by the Data Protection Commission
  - 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 the security of all 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 Data is managed, stored and destroyed 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 Data.

9. The Parties will ensure that all relevant staff are appropriately trained to handle and process shared Data in accordance with the technical and organisational measures in their own computing and manual filing infrastructures. The Parties shall ensure that all relevant staff are aware and act in compliance with this Agreement and this will be supported by the implementation of appropriate policies and procedures.
10. The Parties agree not to transfer any Data outside the European Union except in accordance with the conditions laid down in Article 44 of the GDPR
11. The Parties will ensure that all 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. 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.
13. The Parties agree to comply with the Section 9 of this Agreement in the event of a data subject request.

SIGNED on behalf of the  
**Health Information and Quality  
Authority**



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Phelim Quinn  
Chief Executive Officer

Date: 8<sup>th</sup> October 2021

SIGNED on behalf of  
**The Environmental  
Protection Agency**



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Tom Ryan  
Director, EPA Office of  
Environmental Enforcement

Date: 8<sup>th</sup> October 2021