Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

epa
Environmental Protection Agency

Memorandum of Understanding

Health Information and Quality Authority

and

Environmental Protection Agency

February 2020

1. Background

1.1 The Health Information and Quality Authority (HIQA) having its head office at Unit 1301 City Gate, Mahon, Cork, Ireland and the Environmental Protection Agency (EPA) having its head office at PO Box 3000, Johnstown Castle Estate, Co. Wexford, Ireland ("the Parties") wish to establish a framework for cooperation and information sharing in areas of mutual responsibility and shared interest which fall within their respective remits.

1.2 HIQA, having been established under the Health Act 2007 (as amended), is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public. HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for setting standards for health and social services, regulating social care services, monitoring health services and children's social services, evaluating the clinical and costs effectiveness of health technologies, advising on the efficient and secure collection and sharing of health information and carrying out national services-user experience surveys in conjunction with the Department of Health and the HSE through the National Care Experience Programme. HIQA is now also responsible for the regulation of medical exposures to ionising radiation.

1.3 The EPA, having been established under the Environmental Protection Agency Act 1992, is an independent public body responsible for protecting people and the environment from the harmful effects of radiation. The EPA's mission in "*to protect and improve the environment as a valuable asset for the people of Ireland. To protect our people and the environment from the harmful effects of radiation and pollution.*" The functions of the EPA concerning radiological protection are set out in the Radiological Protection Act, 1991 (as amended) and the corresponding Regulations. The Radiological Protection (Miscellaneous Provisions) Act 2014 transferred the functions previously held by the Radiological Protection Institute of Ireland to the EPA. The EPA is responsible for authorising practices involving the use of ionising radiation, inspection of authorised facilities to assure compliance and assessing the exposure of people in Ireland to ionising radiation.

1.4 Irish Regulations concerning the use of ionising radiation are derived directly from the European Union Basic Safety Standards (BSS) Directive (Council Directive 2013/59/EURATOM)(the Directive). The Directive has been

transposed into Irish law by the following Regulations (collectively referred to as the Regulations):

- the Ionising Radiation Regulations, 2019 (S.I. No. 30 of 2019), which concern the protection of workers and members of the public. The EPA is the Competent Authority for these regulations and
- the European Union (Basic Safety Standards for protection against dangers arising from medical exposure to ionising radiation) Regulations 2018 (S.I. No. 256 of 2018) (as amended), which concerns the protection of patients, asymptomatic individuals and carers and comforters during medical exposures. HIQA is the Competent Authority for Articles 55, 60, 63, 76, 77, 96, 104 and 105 of the Directive, in so far as those Articles relate to medial exposures, as outlined in Section 3(1) of S.I. 256 of 2018.

In order to legally carry out medical radiological procedures in Ireland, it is necessary to comply with the Regulations

2. Objectives

2.1 This Memorandum of Understanding (MOU) is intended to assist and support both HIQA and the EPA in performing their separate but parallel functions under the Regulations. In particular, it takes note of areas of potential cooperation and collaboration required to fulfil each Parties functions under the Regulations.

2.2 The objectives of this MOU are:

a) To promote cooperation in areas of strategic and operational interest;
b) To facilitate a coherent and seamless approach by the Parties to the regulated community;
c) To facilitate the fulfilment of interdependent obligations on the Parties referred to in the Regulations;
d) To facilitate cooperation on cross referral of information where one party believes that it falls within the remit of the other (or both);
e) To facilitate the appropriate exchange between the Parties of reliable information related to inspections, escalations and enforcement that may be of relevance to the other party;
f) To share knowledge, expertise and experience in relation to radiation protection;
g) To support areas of regulatory interface between the Parties.

2.3 This MOU represents the understanding reached by the Parties, in particular:

a) That both Parties operate under different regulations as set out in clause 1.3. This MOU is intended to cover areas of common interest where cooperation will lead to safer services and outcomes for people using ionising radiation emitting equipment, patients or asymptomatic individuals exposed to ionising radiation for medical purposes, or other members of the public who could be exposed to ionising radiation, and;

b) That both Parties may, in particular circumstances, limit the scope of disclosure of information only if the disclosure is contrary to the public interest or the interests of the party concerned, is in breach of or is inconsistent with statutory obligations or requirements or other obligations and requirements imposed by law such as data protection legislation.

3. Areas of cooperation

3.1 The Parties undertake to communicate as appropriate on all matters of strategic, mutual and operational interest. Communication will be conducted on both a formal basis through scheduled meetings and on an informal basis. All communications between the Parties pursuant to this MOU will be carried out through the contact persons set out in clause 9.

3.2 The Parties, having reached the above understanding, have agreed to co-operate in the following areas:

(a) Conduct of Inspections

Both Parties have a function in relation to visiting and inspecting undertakings involved in the use of ionising radiation. In conducting inspections, both Parties should be cognisant of each other's activity within that sector. Information on inspection programmes may be exchanged to enable effective scheduling, planning and the delivery of each Party's activity.

(b) Regulatory Interface

While the function of each party is distinct, it is recognised that there are interface areas relevant to both Parties. Where issues arise, such that the requirements of one party may impact on the requirements of the other, then these may be raised through the contact persons set out in clause 9.

(c) Exchange of Information

Where either party becomes aware of matters which are considered to be of concern to the other party, the two Parties will co-operate as far as is reasonably practicable to ensure that the attention of the other party is drawn to the matter in question in a timely manner.

(d) Escalation & Enforcement

Both Parties have enforcement responsibilities in respect of undertakings who have contravened a provision of the Regulations. Each party will be aware and cognisant of each other's activity in relation to compliance notices, enforcement notices, prohibition orders and withdrawal of authorisation, registration or licences. Information relating to the foregoing activities may be exchanged to enable each party to carry out its functions under their respective regulations.

4. Confidentiality

4.1 Before transferring any information or personal data, each party will satisfy itself that any such transfer is not in breach of its own legislative provisions regarding confidentiality and/secrecy, or in breach of any other relevant statutory provisions, including the Data Protection Acts 1988 to 2018 and the General Data Protection Regulation 2016/679. Where information can usefully be anonymised before being transferred, each party will do so. Both Parties recognise the prime importance of protecting service users and thus want to facilitate effective and timely information exchange designed to secure this outcome where appropriate.

4.2 Except as required or permitted by law, information shared between the Parties will not be provided to third parties without the written consent of the other party. The information disclosed by either party will not be used for any other purpose other than the performance of the party's statutory functions.

4.3 The Parties have entered into a Data Sharing Agreement with each other which will be published on each party's website.

5. Financial arrangements

Each party to the MOU will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

6. Variation

Any provision of this MOU may be amended at any time by the mutual consent in writing of the Parties via the respective signatories.

7. Status of Memorandum of Understanding

This MOU reflects the intentions of the Parties. Each party acknowledges it is not intended to create any legally binding obligations of any nature, save for the obligations to maintain the confidentiality of information described in clause 4 and those set out in the Regulations

8. Effective date and review

8.1 This MOU will come into effect on the date of the last signature of this MOU by the Parties and will continue in effect until its termination in accordance with clause 10.

8.2 This MOU will be subject to a formal review by the Parties every two years from the date of its signing or otherwise as requested by a party to this MOU. The content of the MOU will be reviewed to ensure that it remains relevant, fit for purpose and up to date. Following the review, any required variations arising therefrom will be made in accordance with clause 6.

9. Contact Persons

9.1 The contact persons responsible for the operation of this MOU are:

HIQA Contact:

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

EPA Contact:

The designated EPA Programme manager with responsibility for ionising radiation regulation.

9.2 Upon signing this MOU, each party will ensure that the identity and contact details (email and telephone number) of the persons referred to above will be exchanged with the other party. In the event that there is a change in the identity of a contact person referred to above during the term of this MOU, the relevant party will inform the other party of same and will forward the contact details of the replacement contact person as soon as practicable.

10. Termination

a) Either party may, at any time, give written notice of termination to the other party. This MOU (excepting clause 4) will terminate six months after the date of receipt of the notice of termination.

b) The termination of this MOU will not affect the confidentiality undertakings expressed by the Parties in this MOU or any commitments given under, or as a consequence of, this MOU in respect of any arrangements or action taken during the period before the termination takes effect.

Signed by Phelim Quinn

Chief Executive Officer for and on behalf of

Health Information and Quality Authority

Date: 3 FEBRUARY 2020.

Signed by Laura Burke

Director General for and on behalf of

Environmental Protection Agency

Date: 3/2/2020