



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Regulation of
Health and Social
Care Services

Regulatory Notice

Clarification of the definition of an
undertaking in the medical exposure to
ionising radiation regulations

Updated September 2019

Safer Better Care

Introduction

This updated Regulatory Notice (the 'Notice') has been developed to provide guidance on the definition of an 'undertaking' under the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 (the 'Regulations').* The Notice replaces HIQA's previous notices issued in April 2019 and June 2019 relating to this matter.

The Notice can be used to help determine what constitutes an undertaking for the purposes of the Regulations. It should be read in conjunction with the *Undertaking information handbook*, which is available at www.hiqa.ie.

While the Notice is intended to be of assistance, responsibility in law rests with the individual or entity to determine what constitutes an undertaking under the Regulations.

The Regulations

In the Regulations, an undertaking is the term used to describe a person or entity that has overall responsibility for carrying out or engaging others to carry out medical radiological procedures. The Regulations set out particular obligations on an undertaking. Failure to comply with these obligations can constitute an offence under Part 6 of the Regulations.

An undertaking is obliged to notify HIQA of its existence under the Regulations. This must be done by submitting a declaration of undertaking form, which is available [here](#). Any *new* undertaking intending to commence practices must notify HIQA one month before the proposed commencement by submitting a declaration of undertaking form to HIQA.

Definition of an undertaking

In the Regulations, an undertaking is defined as:

a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure.

* *Laws, rules and regulations may change from time to time. HIQA reserves the right to revise, amend, alter or delete the information provided in this Notice.*

HIQA considers each of the following scenarios to constitute an undertaking under the Regulations:

1. A healthcare provider[†] who carries out, or employs others to carry out, a medical radiological procedure is an undertaking and is responsible for compliance with the Regulations.
2. A healthcare provider who engages others to carry out a medical radiological procedure is the undertaking and is responsible for compliance with the Regulations.

Healthcare providers should carefully consider points 1-2 above when making their declaration of undertaking. In making the declaration, the healthcare provider must satisfy itself that, irrespective of the manner of engagement or employment with those that carry out medical radiological procedures, the undertaking must have robust oversight arrangements in place to ensure that those carrying out medical radiological procedures comply with the Regulations and in so doing the healthcare provider itself accepts responsibility for compliance with the Regulations.

Further information

Should you have any further queries in relation to the above information or the definition of undertaking as it applies to your practice, please contact HIQA at radiationprotection@hiqa.ie.

[†] For the purpose of this Regulatory Notice, a healthcare provider means any sole trader, company, partnership, unincorporated body, body corporate or statutory body that carries out or engages others to carry out medical radiological procedures as defined in Section 2 of the Regulations. This may include but is not limited to; hospitals, healthcare clinics, dental practices or sole trader practitioners.



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