

## STATUTORY INSTRUMENTS.

S.I. No. 280 of 2025

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) (AMENDMENT) (NO. 2) REGULATIONS 2025

## S.I. No. 280 of 2025

EUROPEAN UNION (BASIC SAFETY STANDARDS FOR PROTECTION AGAINST DANGERS ARISING FROM MEDICAL EXPOSURE TO IONISING RADIATION) (AMENDMENT) (NO. 2) REGULATIONS 2025

I, JENNIFER CARROLL MACNEILL, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Directive (EU) 2013/59/EURATOM of 5 December 2013<sup>1</sup>, as affected by Corrigendum of 17 March 2016<sup>2</sup> and Corrigendum of 11 June 2019<sup>3</sup>, insofar as it relates to medical exposures, hereby make the following regulations:

- 1. (1) These Regulations may be cited as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) (Amendment) (No. 2) Regulations 2025.
- (2) The citation "the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 to 2025" includes these Regulations.
- 2. In these Regulations "Principal Regulations" means 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).
- 3. Regulation 8(5) of the Principal Regulations is substituted by the following:
- "(5) An undertaking shall ensure that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease—
  - (a) the procedure -
    - (i) is part of a health screening programme, or
    - (ii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer, in accordance with guidelines published by the Authority in accordance with paragraph (6), and
  - (b) special attention is given to the provision of information to the individual, as required by paragraph (13).".

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<sup>&</sup>lt;sup>1</sup> OJ No. L 13, 17.1.2014, p. 1.

<sup>&</sup>lt;sup>2</sup> OJ No. L 72, 17.3.2016, p. 69.

<sup>&</sup>lt;sup>3</sup> OJ No. L 152, 11.6.2019, p. 128.



GIVEN under my Official Seal, 25 June, 2025.

JENNIFER CARROLL MACNEILL, Minister for Health.

## **EXPLANATORY NOTE**

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018.

This amendment makes more explicit the requirement to comply with guidelines published by the Health Information and Quality Authority when making a documented justification for a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease, and with being in accord with guidelines.

These Regulations may be cited as the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) (Amendment) (No. 2) Regulations 2025.

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