

L.N. 139 of 2022**NUCLEAR SAFETY AND RADIATION PROTECTION ACT
(CAP. 585)****Basic Safety Standards for Ionising
Radiation (Amendment) Regulations, 2022**

IN EXERCISE of the powers conferred by article 62 of the Nuclear Safety and Radiation Protection Act, the Minister for Inclusion, Voluntary Organisations and Consumer Rights has made the following regulations:-

1. The title of these regulations is the Basic Safety Standards for Ionising Radiation (Amendment) Regulations, 2022 and these regulations shall be read and construed as one with the Basic Safety Standards for Ionising Radiation Regulations, hereinafter referred to as "the principal regulations". Citation.
S.L. 585.01.

2. Sub-regulation (2) of regulation 9 of the principal regulations shall be substituted by the following new sub-regulation: Amends
regulation 9 of
the principal
regulations.

"(2) The limit on effective dose for occupational exposure shall be 20mSv in any single year. In special circumstances or for certain exposure situations where the Secretariat is satisfied that a dose in excess of the annual limit is appropriate, the Secretariat may authorise a higher effective dose of up to 50mSv in a single year, provided that the average annual dose over any five (5) consecutive years, including the years for which the limit has been exceeded, does not exceed 20mSv."

3. Sub-regulation (2) of regulation 12 of the principal regulations shall be substituted by the following new sub-regulation: Amends
regulation 12 of
the principal
regulations.

"(2) The limit of the effective dose for public exposure is 1mSv per annum."

4. Regulation 31 of the principal regulations shall be amended as follows: Amends
regulation 31 of
the principal
regulations.
 - (a) paragraph (a) of sub-regulation (1) thereof shall be substituted by the following new paragraph:

"(a) the practice is subject to licensing by the Commission and shall impose specific requirements, including criteria for individual implementation, that have been established by the Commission, making reference to

guidance available from international bodies, in cooperation with Maltese professional bodies of practitioners, other governmental regulatory bodies and any other such persons or bodies that the Commission sees fit as appropriate;"; and

(b) sub-regulation (2) thereof shall be substituted by the following new sub-regulation:

"(2) For procedures not using medical radiological equipment, shall have dose constraints that shall be established by the Commission and its value shall not exceed an effective dose of 0.005mSv per procedure with a limit of 0.1mSv per year for the individual exposed to that procedure and;".

Amends regulation 34 of the principal regulations.

5. Sub-regulation (1) of regulation 34 of the principal regulations shall be substituted by the following new sub-regulation:

"(1) Notification is required for all justified practices, including those identified according to regulation 33. The notification shall be made at least thirty (30) days prior to a practice commencing. Existing practices shall notify within thirty (30) days of the publication of this regulation. The Secretariat shall specify the information to be provided in conjunction with the notification. Where an application for an authorisation is submitted, no separate notification is needed. An authorisation may lead to the Secretariat issuing the undertaking with either a registration or license."

Substitutes regulation 36 of the principal regulations.

6. Regulation 36 of the principal regulations shall be substituted by the following new regulation:

"36. (1) The Commission shall require either registration or licensing of the following practices:

(a) the operation of radiation generators or accelerators or radioactive sources for medical exposures or for non-medical imaging exposure purposes; and

(b) the operation of radiation generators or accelerators, except electron microscopes, or radioactive sources for purposes not covered by sub-paragraph (a).

(2) The Commission may require registration or licensing of other types of practices.

(3) Subject to regulation 37, the Commission shall, in accordance with sub-regulations (1) and (2), determine which practices are subject to registration or licensing. The Commission shall base its decision to submit a type of practice to registration or licensing, using a graded approach and based on regulatory experience taking into account:

- (a) the magnitude of expected or potential doses resulting from the practice;
- (b) the impact that regulatory control may have in reducing such doses or improving radiological safety;
- (c) the complexity of the practice; and
- (d) safety and security having regard to the circumstances in which the relevant practice is proposed to be carried out."

7. Sub-regulation (2) of regulation 44 of the principal regulations shall be substituted by the following new sub-regulation:

Amends regulation 44 of the principal regulations.

"(2) For workplaces specified in regulation 64(3) and where the exposure of workers is liable to exceed an effective dose of 6mSv per year or a corresponding time-integrated radon exposure value to be determined by the Commission based on international guidance, these shall be managed as a planned exposure situation and the Commission shall determine which requirements set out in this Part VI are appropriate. For workplaces specified in regulation 64(3), and where the effective dose to workers is less than or equal to 6mSv per year, or the exposure less than the corresponding time integrated radon exposure value for the workers, the Commission shall require that exposures are kept under review."

8. Regulation 45 of the principal regulations shall be substituted by the following new regulation:

Substitutes regulation 45 of the principal regulations.

"45. (1) Undertakings shall ensure that workplaces are designated as either controlled or supervised, where appropriate, on the basis of the safety assessment, made pursuant to regulation 101, of the expected annual doses and the probability and magnitude of potential exposures.

(2) Undertakings shall refer to the Commission guidance on the classification of controlled and supervised areas with regard to particular circumstances.

(3) Undertakings shall designate as a controlled area any area under their control which:

(a) it is necessary for any person who enters or works in the area to follow special procedures designed to restrict significant exposure to ionising radiation in that area or prevent or limit the probability and magnitude of radiation accidents or their effects; or

(b) any person working in the area is likely to receive an effective dose greater than 6mSv a year or an equivalent dose greater than three-tenths of any relevant dose limit referred to in these regulations.

(4) Undertakings shall designate as a supervised area any area under their control, not being an area designated as a controlled area:

(a) where it is necessary to keep the conditions of the area under review to determine whether the area should be designated as a controlled area; or

(b) in which any person is likely to receive an effective dose greater than 1mSv a year or an equivalent dose greater than one-tenth of any relevant dose limit referred to in these regulations.

(5) On the basis of the documentation supplied, including the Safety Assessment, by the undertaking to the Commission, the Secretariat shall confirm that the appropriate area classification has been made."

Amends
regulation 66 of
the principal
regulations.

9. Sub-regulation (3) of regulation 66 of the principal regulations shall be substituted by the following new sub-regulation:

"(3)(a) The Commission shall establish and regularly review national diagnostic reference levels for radio-diagnostic examinations, having regard to the current European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

(b) An undertaking shall ensure that diagnostic reference levels for their radio-diagnostic examinations, and where appropriate for interventional radiology procedures, are established, regularly reviewed and used, having regard to the national diagnostic reference levels where available."

10. Regulation 85 of the principal regulations shall be substituted by the following new regulation:

Substitutes regulation 85 of the principal regulations.

"Planning for the protection of members of the public.

85. (1) Undertakings shall take such measures as are necessary to ensure the operational protection of members of the public in normal circumstances having regard to the relevant provisions of these regulations.

(2) For the purposes of these regulations, "operational protection of members of the public" means, in normal circumstances, all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation, may result in actual or potential exposure to members of the public exceeding the relevant dose constraint such that the exposure from any one practice is not liable to exceed 0.25mSv in a year.

(3) For relevant activities, the Commission shall before granting a registration or a licence in respect of a practice or amending any condition attached to a registration or specified in a licence, or acceptance into service of a facility, require the undertaking to submit to it for examination and approval:

(a) the proposed siting of the workplaces from a radiation protection point of view, taking into account relevant demographic, meteorological, geological, hydrological and ecological conditions;

(b) a statement of planned arrangements to ensure adequate protection against any exposure or radioactive contamination liable to extend beyond the perimeter of the workplaces or radioactive contamination liable to extend to the ground beneath the facility;

(c) pursuant to regulation 87, plans for the discharge of radioactive effluents;

(d) the results of a screening assessment of the doses liable to be received by the population as a result of any practice carried out by it; and

(e) a statement of planned measures to control the access of members of the public to the facility.

(4) The Commission shall, pursuant to regulation 87, where appropriate, establish limits and conditions on the quantities of radionuclides discharged to air or water during a specified period, which shall take into account:

(a) the results of the optimisation of radiation protection;

(b) good practice in the operation of similar facilities; and

(c) where appropriate, results of generic screening assessment based on internationally recognised scientific guidance, where such an assessment has been required by the Commission."

Amends regulation 96 of the principal regulations.

11. Sub-regulation (2) of regulation 96 of the principal regulations shall be substituted by the following new sub-regulation:

"(2) For areas with long-lasting residual contamination the Commission shall consult entities that have responsibilities for land use planning, land ownership, environmental protection and public health and shall advise the government on allowing habitation and the resumption of social and economic activities, to ensure that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:

(a) establishment of appropriate reference levels;

(b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring;

(c) if appropriate, remedial measures;

(d) if appropriate, delineated areas."

Amends regulation 98 of the principal regulations.

12. Sub-regulations (2) and (3) of regulation 98 of the principal regulations shall be substituted by the following new sub-regulations:

"(2) For building materials which are identified by the Commission as being of concern from a radiation protection point of view, taking into account the indicative list of materials set out in the Twelfth Schedule with regard to their emitted gamma radiation, the Commission shall consult with the entity responsible for placing materials on the market in order that, before such materials are placed on the market:

(a) the activity concentrations of the radionuclides specified in the Seventh Schedule are determined, and that,

(b) information to the Commission on the results of measurements and the corresponding activity concentration index, as well as other relevant factors, as defined in the Seventh Schedule are provided if requested.

(3) For types of building materials identified in accordance with sub-regulation (2) which are liable to give doses exceeding the reference level, the Commission consults the entity responsible for building and construction on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials."

13. Paragraph (a) of sub-regulation (1) of regulation 106 of the principal regulations shall be substituted by the following new paragraph:

Amends regulation 106 of the principal regulations.

"(a) have a degree in radiation protection, physics, engineering, mathematics, radiography or a suitable combination of other qualifications and experience; and".

14. Sub-regulation (1) of regulation 109 of the principal regulations shall be substituted by the following new sub-regulation:

Amends regulation 109 of the principal regulations.

"(1) Medical physics experts shall meet the following criteria for initial certification by the Commission:

(a) be registered by the Council for the Professions complimentary to Medicine in Malta as a medical physicist; and

(b) two (2) years documented full time work experience, within the preceding twenty-eight (28) months, in specialty (radiotherapy, nuclear medicine, diagnostic and interventional radiology) with documented Continuous Professional Development."

15. Regulation 114 of the principal regulations shall be amended as follows:

Amends regulation 114 of the principal regulations.

(a) sub-regulation (3) thereof shall be amended as follows:

(i) the words "Undertakings are required, that in addition to the general licensing requirement set out in Part V, shall have provided for, within its radiation protection programme for:" shall be substituted by the words "The radiation protection programme shall address the following

issues, which are in addition to the general licensing requirements set out in Part V, shall be provided to the Commission when applying for a license:";

(ii) paragraph (m) thereof shall be substituted by the following new paragraph:

"(m) the confidentiality of information relating to the security of sources;" and

(iii) immediately after paragraph (m) thereof there shall be added the following new paragraph:

"(n) any other specific requirement that the Commission may require." and

(b) immediately after sub-regulation (5) thereof there shall be added the following new sub-regulation:

"(6) The Commission shall review the radiation protection programme at the authorisation stage and may impose specific conditions involving the use of high activity sources in any licence that may be issued."

Substitutes
regulation 125
of the principal
regulations.

16. Regulation 125 of the principal regulations shall be substituted by the following new regulation:

"125. (1) The Commission strategy to ensure the appropriate management of existing exposure situations commensurate with the risks and with the effectiveness of protective measures shall consider:

(a) delineation of the affected areas and identification of the affected members of the public;

(b) consideration of the need for and extent of protective measures to be applied to the affected areas and members of the public;

(c) consideration of the need to prevent or control access to the affected areas, or to impose restrictions on living conditions in these areas;

(d) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure;

(e) controls on commodities incorporating radionuclides from the contaminated area;

(f) consideration of the need to ensure that the form, scale and duration of all protective measures in the strategy are optimised; and

(g) provision for cooperation, where appropriate, with entities responsibilities for land use planning, land ownership, environmental protection and public health."

17. Sub-regulation (1) of regulation 126 of the principal regulations shall be substituted by the following new sub-regulation:

Amends regulation 126 of the principal regulations.

"(1) Following consultations with entities responsible for land use planning, land ownership, environmental protection and public health, the Commission shall advise these entities and the government on the implementation of strategies for the management of existing exposure situations, and ensure appropriate coordination between the entities involved in the implementation of remedial and protective measures. Stakeholders shall be involved as appropriate in decisions regarding the development and implementation of strategies for managing exposure situations."

18. Sub-regulation (2) of regulation 127 of the principal regulations shall be substituted by the following new sub-regulation:

Amends regulation 127 of the principal regulations.

"(2) The Commission shall make recommendations to the entity responsible for building and construction on any appropriate measures that may need to be included in the national building codes to reduce radon ingress into new buildings."

19. Section B(1) of the Eleventh Schedule to the principal regulations shall be substituted by the following new section:

Amends the Eleventh Schedule to the principal regulations.

"(1) On the basis of the emergency response plan previously drawn up in the Commission, the members of the public actually affected in the event of an emergency shall rapidly and regularly receive:

(a) information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);

(b) advice on protection, which, depending on the type of emergency, may:

(i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements;

(ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public;

(c) announcements recommending cooperation with instructions or requests."
