

L.N. of 2019

**NUCLEAR SAFETY AND RADIATION PROTECTION ACT
(CAP. 585)**

Management of Radioactive Waste Regulations, 2019

IN EXERCISE of the powers conferred by article 62 of the Nuclear Safety and Radiation Protection Act, the Minister has made the following regulations:-

Title and Commencement.

1. (1) The title of these regulations is the Management of Radioactive Waste Regulations, 2019.
- (2) These regulations shall come into force on the **XXXX**

Scope.

2. (1) The objective of these regulations is to ensure that radioactive waste is managed in a manner that protects human health and the environment now and in the future, without imposing undue burdens on future generations.

(2) These regulations provide the arrangements for safety in radioactive waste management to protect workers and the general public against the dangers arising from ionising radiation.

(3) These regulations shall apply to all stages of: radioactive waste management, from generation to disposal, when the radioactive waste results from civilian activities.

(4) These regulations provide for the necessary public information and participation in relation to radioactive waste management while having due regard to security and proprietary information.

(5) These regulations shall bring into effect the provisions of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste and the International Atomic Energy Agency's Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

(6) These regulations provide additional measures, procedures and guidance to those mentioned in Basic Safety Standards for Ionising Radiation Regulations, 2018. *(to insert SL585 .01 in margin)*

Application.

3. (1) These regulations shall apply to all radioactive waste with the exception of:

(a) releases authorised by virtue of regulation 87 of Basic Safety Standards for Ionising Radiation Regulations, 2018; *(to insert SL585.01 in margin)*

(b) waste that may be radioactive which falls within the scope of the Waste Management (Management of Waste from Extractive Industries and Backfilling) Regulations, 2009; *(to insert SL549.50 in margin)*

(2) Regulation 15 shall not apply to repatriation of disused sealed sources to a supplier or manufacturer;

(3) These regulations allow for the return of radioactive waste after processing in Malta to its country of origin where:

(a) the radioactive waste is to be shipped to that Member State or undertaking for processing; or

(b) other material is to be shipped to that Member State or undertaking with the purpose of recovering the radioactive waste.

Interpretation.

4. For the purpose of these regulations, the following definitions shall apply:

“Act” means the Nuclear Safety and Radiation Protection Act *(to insert CAP 585);*

“closure” means the completion of all operations at some time after the emplacement of radioactive waste in a disposal facility, including the final engineering or other work required to bring the facility to a condition that will be safe in the long term;

"Commission" means the Commission for the Protection from Ionising and Non-Ionising Radiation, as established by article 10 of the Act which acts as the regulatory authority in the field of nuclear safety and radiation protection and has the legal authority for the purpose of these regulations;

“disposal” means the emplacement of radioactive waste in a facility without the intention of retrieval;

“disposal facility” means any facility or installation the primary purpose of which is radioactive waste disposal;

“licence” means a legal document issued by the Commission related to the management of radioactive waste, or to confer responsibility for siting, design, construction, commissioning, operation, decommissioning or closure of a radioactive waste management facility;

“licence holder” means a legal or natural person having overall responsibility for any activity or facility related to the management of radioactive waste as specified in a licence;

"Minister" means the minister responsible for the Act;

“radioactive waste” means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Commission.;

“radioactive waste management” means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation;

“radioactive waste management facility” means any facility or installation the primary purpose of which is radioactive waste management;

“Secretariat” means the Secretariat to the Commission, as established by article 12 of the Nuclear Safety and Radiation Protection Act. *(to insert Cap585 in margin)*

“storage” means the holding of radioactive waste in a facility with the intention of retrieval.

Radioactive Waste Management Programme

5. (1) There shall be a national programme for the management of radioactive waste in Malta entitled the Radioactive Waste Management Programme.

(2) The objective of the radioactive waste management programme is to enable radioactive waste to be treated in a sustainable manner that protects human health and the environment now and in the future without imposing undue burdens on future generations.

(3) The radioactive waste management programme shall include policies and strategies for the management of radioactive waste. The policies shall reflect priorities, circumstances, structures, and available human and financial resources whilst the strategies shall implement the policies.

(4) The radioactive waste management programme shall consider :

(i) All stages of radioactive waste management, from generation to disposal;

(ii) The concepts or plans for the post-closure period of a disposal facility’s lifetime, including the period during which appropriate controls are retained and the means to be employed to preserve knowledge of that facility in the longer term;

(iii) Research, development and demonstration activities that are needed in order to implement solutions for the management of spent fuel and radioactive waste;

(6) In the event that radioactive waste is sent overseas for processing, the ultimate responsibility for the safe and responsible disposal of those materials, will remain in Malta or the other country from which the radioactive material was shipped.

6. Radioactive policies referred to in regulation 5(3) shall take into due account:

(1) Requirement for the minimisation of activity and volume of radioactive waste and shall include the options to recycle and reuse of materials.

(2) The need to consider the interdependencies between all steps in radioactive waste generation and management, including the need for the appropriate conditioning of waste.

(3) The use of passive safety features for the long term management of radioactive waste.

(4) The need for the implementation of measures to follow a graded approach;

(5) The need that the radioactive waste management can be financed in the long term;

(6) The need for evidence-based and documented decision-making process to be applied with regard to all stages of the management of radioactive waste;

(7) That Radioactive waste shall be disposed of in the Member State in which it was generated, unless at the time of shipment an agreement, taking into account the Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, (*insert SL 549.51 in margin*), has entered into force between Malta and another country to use a disposal facility in one of them;

(8) That radioactive waste (stipulated in regulation 3) shall be managed in the long term by an entity independent from the Commission and licensed by the Commission

(9) Public and workers involvement in decision making process.

In particular :

(i) The necessary information on the management of radioactive waste be made available to workers and the general public. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

(ii) Ensure that the public be given the necessary opportunities to participate effectively in the decision- making process regarding radioactive waste management in accordance with national legislation and international obligations

(10) Gaining control over sources that are out of regulatory control

(11) Methodology for setting discharge limits from nuclear medicine departments.

Financing the radioactive waste management programme

7. The Commission shall provide the Minister with estimates of the costing of the radioactive waste management programme

The estimates shall include an assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time.

8. (1) Licence holders are responsible for their radioactive waste and through the polluter pays principle and are responsible for all financing of the management of their waste.

(2) Licensed holders of waste may be charged for the storage and disposal of radioactive waste.

Responsibility for waste in the case there is no license holder

9. If there is no licence holder for a source or other responsible party, the responsibility for the source rests with the government of Malta.

Radioactive waste management facilities

10. In connection with radioactive waste management facilities due consideration will be given, but will not be limited to:

- a. The siting of the facility
- b. Design and construction aspects of the facility
- c. Safety and environmental assessments
- d. Operational aspects
- e. Post closure aspects

Licensing of radioactive waste management activities and facilities

11. (1) All radioactive waste management activities and facilities shall require a license to be issued by the Commission.

Role of the Commission.

12. (1) The Commission shall have overall responsibility for the implementation of these regulations.

(2) The Commission shall develop and maintain national Radioactive Waste Management Programme

(3) The Commission shall in particular have the following functions with respect to these regulations

(a) To advise the Minister on financial issues relating to the radioactive waste management programme.

(b) To advise the Minister on assignment of responsibilities to various stakeholders

(c) The responsibility for the monitoring of the radioactive waste management programme key performance indicators The key performance indicators shall include the significant milestones to achieve the permanent solution (including central storage and disposal) and timeframes for the achievement of those milestones.

(d) Maintain an inventory of all radioactive waste and estimates for future quantities, indicating the location and amount of the radioactive waste in accordance with appropriate classification of the radioactive waste as required.

(e) Provide a system of appropriate licencing of radioactive waste management activities, including appropriate measures for the post-closure periods of disposal facilities;

(f) Perform enforcement actions, including the suspension of activities and the modification, expiration or revocation of a licence together with requirements, if appropriate, for alternative solutions that lead to improved safety;

(g) Seek to improve the national framework, taking into account operating experience, insights gained from the decision-making process referred to in Regulation 6(6) of these Regulations, and the development of relevant technology and research.

(h) Perform reviews and update as required its national programme, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews

(i) Notify to the European Commission of the national programmes and any subsequent significant changes.

(j) Report to the European Commission on the implementation of this Directive for the first time by 23 August 2015, and every 3 years thereafter, taking advantage of the review and reporting under the Joint Convention.

(k) Respond to any request from the European Commission for any clarification made in connection with the national programme.

(l) At least every 10 years, arrange for self-assessments of their national framework, competent regulatory authority, national programme and its implementation, and invite

international peer review of their national framework, competent regulatory authority and/or national programme with the aim of ensuring that high safety standards are achieved in the safe management of radioactive waste. The outcomes of any peer review shall be reported to the European Commission and the other Member States, and may be made available to the public where there is no conflict with security and proprietary information.

(m) Comply with the Maltese reporting requirements and full attendance of meetings under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

Training

13. (1) The Commission shall ensure that the members of its Secretariat have sufficient understanding of the safety and security aspects related to management of radioactive waste. In particular the Commission shall ensure that members of the Secretariat have participated in on going training.

(2) During the licensing process by the Commission, the Secretariat shall require that arrangements for education and training have been undertaken by potential license holders.

Duties of Licence holders

14. (1) The prime responsibility for the safety of radioactive waste management facilities and/or activities rest with the licence holder.

(2) Licence holders are to regularly assess, verify and continuously improve, as far as is reasonably achievable, the safety of the radioactive waste management facility or activity in a systematic and verifiable manner. This shall be achieved through an appropriate safety assessment, other arguments and evidence.

(3) As part of the licensing of a facility or activity the safety demonstration shall cover the development and operation of an activity and the development, operation and decommissioning of a facility or closure of a disposal facility as well as the post-closure phase of a disposal facility. The extent of the safety demonstration shall be commensurate with the complexity of the operation and the magnitude of the hazards associated with the radioactive waste, and the facility or activity. The licensing process shall contribute to safety in the facility or activity during normal operating conditions, anticipated operational occurrences and design basis accidents. It shall provide the required assurance of safety in the facility or activity. Measures shall be in place to prevent accidents and mitigate the consequences of accidents, including verification of physical barriers and the licence holder's administrative protection procedures that would have to fail before workers and the general public would be significantly affected by ionising radiation. That approach shall identify and reduce uncertainties.

(4) Licence holders establish and implement integrated management systems, including quality assurance, which give due priority for overall management of radioactive waste to safety and are regularly verified by the Commission

(5) Licence holders are to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of radioactive waste management as laid down in paragraphs 1 to 4.

Waste shipments to third countries

15. Prior to a shipment to a third country, the Commission shall inform the European Commission of the content of any such agreement and take reasonable measures to be assured that:

(a) the country of destination has concluded an agreement with the Community covering radioactive waste management or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;

(b) the country of destination has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by this Directive;

(c) the disposal facility in the country of destination is authorised for the radioactive waste to be shipped, is operating prior to the shipment, and is managed in accordance with the requirements set down in the radioactive waste management and disposal programme of that country of destination.

Enforcement.

15. (1) The Commission shall enforce these regulations .

(2) Any breach of any of these regulations shall be deemed an offence.

(3) In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, it shall be for the accused to prove, as the case may be, that it was not practicable to do more than was in fact done to satisfy the requirement or duty, or that there was no better practicable means than was in fact used to satisfy the duty or requirement.

Repeal

16. The Convention on Nuclear Safety Regulations are hereby repealed. *(SL365.45 in margin)*