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L.N. 186 of 2013**NATIONAL INTEREST (ENABLING POWERS) ACT
(CAP. 365)****Management of Radioactive Waste Regulations, 2013**

IN exercise of the powers conferred by article 3 of the National Interest (Enabling Powers) Act, the Prime Minister has made the following regulations:-

Citation and commencement.

1. (1) The title of these regulations is the Management of Radioactive Waste Regulations, 2013.

(2) These regulations shall come into force on the 23rd August 2013.

Objective.

2. The aim 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.

Scope.

3. (1) 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.

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

(3) 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 issues.

(4) These regulations 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.

S.L. 365.15

(5) These regulations provide additional measures, procedures and guidance to those mentioned in the Nuclear Safety and Radiation Protection Regulations.

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

(a) releases authorised by virtue of regulation 19(4) of the Nuclear Safety and Radiation Protection Regulations; and S.L. 365.15

(b) waste which may be radioactive which falls within the scope of the Waste Management (Management of Waste from Extractive Industries and Backfilling) Regulations. S.L. 504.87

(2) Regulation 10 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.

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

"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;

"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 Radiation Protection Board 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;

"Radiation Protection Board" means the Radiation Protection Board established by virtue of regulation 9 of the Nuclear Safety and S.L. 365.15

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Radiation Protection Regulations;

"radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Radiation Protection Board;

"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;

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

National
Programme,
Policy and
Strategy.

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

(2) The Radiation Protection Board has the responsibility for the management of radioactive waste through the actions of its member entities and through the radioactive waste national programme. This programme includes a national policy and strategy for the management of radioactive waste. The policy reflects the Maltese priorities, circumstances, structures, and available human and financial resources whilst the strategy shall implement the policy.

(3) The national programme shall consider all stages of radioactive waste management, from generation to disposal.

(4) The responsibility of the coordination of the implementation of the national programme rests with the Radiation Protection Board (RPB).

(5) 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; and

(e) post-closure aspects.

(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.

(7) The policy and strategy shall specify:

(a) the requirement for the minimisation of radioactive waste; generation of radioactive waste shall be kept to the minimum which is reasonably practicable, both in terms of activity and volume, by means of appropriate design measures and of operating and decommissioning practices, including the recycling and reuse of materials;

(b) the interdependencies between all steps in radioactive waste generation and management shall be taken into account;

(c) the use of passive safety features for the long term management of radioactive waste;

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

(e) the requirements for on-site and off-site emergency plans;

(f) financing systems for the management of waste including the polluter pays principle;

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

(h) 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, has entered into force between Malta and another country to use a disposal facility in one of them; S.L. 504.38

(i) that radioactive waste (stipulated in regulation 4) shall be centrally managed waste in the long term;

(j) the significant milestones to achieve the permanent

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solution (including central storage and disposal) and timeframes for the achievement of those milestones. These milestones will include:

- (i) the setting up of a central storage facility;
- (ii) disposal of radioactive waste;
- (k) 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;
- (l) the assignment of responsibilities to the various stakeholders;
- (m) research, development and demonstration activities that are needed in order to implement solutions for the management of radioactive waste;
- (n) an assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;
- (o) financing schemes;
- (p) public information, involvement and transparency policy or process:
 - (i) 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) to 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;
- (q) gaining control over sources that are out of regulatory control;
- (r) source recovery plan;

(s) if there is no licence holder for a source or other responsible party, the responsibility for the source rests with the Government of Malta;

(t) requirements for waste conditioning;

(u) return of new sealed sources;

(v) discharges from nuclear medicine departments;

(w) require all parties to make arrangements for education and training for their staff, as well as research and development activities to cover the needs of the national programme for radioactive waste management in order to obtain, maintain and to further develop necessary expertise and skills.

7. (1) The competent authority that shall have overall responsibility for the implementation of these regulations is the Radiation Protection Board, established under regulation 9 of the Nuclear Safety and Radiation Protection Regulations.

Competent authority.

S.L. 365.15

(2) It shall be the joint duty of the member agencies constituting the Board to ensure matters pertaining to these regulations are carried out in close collaboration and as efficiently as possible, and the Occupational Health and Safety Authority shall take the lead in co-ordinating the administrative actions.

8. The functions of the Board with respect to these regulations shall be to:

Functions of the Board.

(a) be responsible for the establishment and implementation of the national programme and the key performance indicators to monitor progress towards implementation;

(b) to assess the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;

(c) advise the Prime Minister pursuant to regulation 9(3)(b) of the Nuclear Safety and Radiation Protection Regulations, on the allocation of responsibility to the bodies involved in the different steps of radioactive waste management; in particular, the national framework shall give primary responsibility for radioactive waste to their generators or, under specific circumstances, to a licence holder to whom this responsibility has been entrusted by competent bodies;

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(d) advise the Prime Minister pursuant to regulation 9(3)(b) of the Nuclear Safety and Radiation Protection Regulations on the finance required for the national programme;

(e) 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;

(f) licence of radioactive waste management activities, facilities or both, including the prohibition of radioactive waste management activities, of the operation of a radioactive waste management facility without a licence or both and, if appropriate, prescribing conditions for further management of the activity, facility or both;

(g) provide a system of appropriate control, a management system, regulatory inspections, documentation and reporting obligations for radioactive waste management activities, facilities or both, including appropriate measures for the post-closure periods of disposal facilities;

(h) 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;

(i) seek to improve the national framework, taking into account operating experience, insights gained from the decision-making process referred to in regulation 6(7)(g), and the development of relevant technology and research;

(j) 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;

(k) notify the national programme and any subsequent significant changes to the Commission;

(l) report to the Commission on the implementation 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, for the first time by 23 August 2015, and every three years thereafter, taking advantage of the review and reporting under the Joint Convention;

(m) respond to any request from the Commission for any clarification made in connection with the national programme;

(n) at least every ten years, arrange for self-assessments of the national framework, Radiation Protection Board, national programme and its implementation, and invite international peer review of the national framework, Radiation Protection Board 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 Commission and the other Member States, and may be made available to the public where there is no conflict with security and proprietary information;

(o) meet the Maltese reporting requirements and attend meetings under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;

(p) require that 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 Radiation Protection Board.

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

(2) Licence holders shall 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) (a) 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.

(b) The licensing process shall contribute to safety in the facility or activity during normal operating conditions, anticipated

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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 shall establish and implement integrated management systems, including quality assurance, which give due priority for overall management of radioactive waste to safety.

(5) Licence holders shall 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 sub-regulations (1) to (4).

Waste
shipments to
third countries.

10. Prior to a shipment to a third country, the Radiation Protection Board shall inform the 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 ("the Joint Convention");

(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 these regulations;

(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.

Financing by
licence holders.

11. 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.

Enforcement.

12. (1) The member agencies of the Radiation Protection Board shall enforce their respective regulatory functions within their remit of matters pertaining to these regulations through their respective powers.

(2) 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.

13. Any person who commits an offence against these regulations shall, on conviction, be liable to imprisonment for a period of not more than five years or to a fine (*multa*) not exceeding one hundred and sixteen thousand four hundred and sixty-eight euro (€116,468), or to both such imprisonment and fine.

Offences and penalties.

14. The Court of Magistrates (Malta) and the Court of Magistrates (Gozo) as courts of criminal judicature, shall, notwithstanding the provisions of article 370 of the Criminal Code, be competent to try all offences against these regulations.

Procedures before Malta and Gozo Courts. Cap. 9.

15. Where the facts constituting a breach of any of the above provisions also constitute a breach of any other law prohibited by the particular regulations, proceedings shall not be taken in respect of the breach of these regulations, but only in respect of the breach of the other law.

Proceedings in respect of any other law.

