

National Report by Malta

**Made in connection with Article 9.1 of Council Directive
2009/71/EURATOM
Community Framework for the nuclear safety of nuclear
installations**

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Introduction

Nuclear Installations.

Malta does not operate, or plan to operate, any form of nuclear installation, as defined by Article 3(1) of the Directive 2009/71/EURATOM.

Usage of Ionising Radiation in Malta

The usage of ionising radiation in Malta is mainly in medical applications with some uses in industry (including non-destructive testing), research and teaching.

Applicability of the Directive to Malta

In view of the fact that Malta does not have any nuclear installations, as defined in the Directive, not all of the Directive Articles are applicable.

Structure of this Report.

The format of the report is based on ENSREG Guidelines of 2019.

Summary of Main Developments since the 2014 Report.

Since the Maltese last Article 9.1 report in 2014, Malta has made substantial progress in improving its legislative and regulatory framework.

Malta has been working and continues to work on the findings of the IRRS mission in 2015 and the follow-up IRRS mission performed in March 2020.

Malta has reformed its legislative and regulatory framework and to this end a dedicated law and regulations have been promulgated.

A new regulatory authority was set up in 2018 in accordance with the Nuclear Safety and Radiation Protection Act called Commission for the Protection from Ionising and Non-Ionising Radiation hereinafter referred to as the Commission.

Reporting Article-by-Article

Article 4. Legislative, Regulatory and Organizational Framework

4.1 Summary

Article 4

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (“national framework”) for the nuclear safety of nuclear installations.

Since the last Article 9.1 report of 2014 Malta has a new legislative structure including a new regulatory authority.

Following the IRRS review mission to Malta in 2015, Malta issued a new nuclear safety and radiation protection law as well as regulations falling under this law as detailed below.

New Law

Nuclear Safety and Radiation Protection Act (CAP 585) (published 2018), hereinafter referred to as the Act <https://legislation.mt/eli/cap/585>

The scope of this Act being to:

- (i) Allow the beneficial and justified uses of ionising and non-ionising radiation;*
- (ii) Provide for adequate protection of people in current and future generations against the harmful effects of ionising radiation and for the safety of radiation sources;*
- (iii) Provide for the physical protection of nuclear material;*
- (iv) Provide a mechanism whereby these objectives are achieved through the establishment of a Radiation Protection Commission and its Secretariat hereinafter referred to as the “Commission” and “Secretariat”, to act as the competent national authority in the field of nuclear safety and radiation protection.*

New Regulations

Basic Safety Standards for Ionising Radiation Regulations (SL 585.01) (published 2018) hereinafter referred to as the BSS Regulations <https://legislation.mt/eli/sl/585.1>

The Subject matter and scope of these regulations is given in regulation 2 as:

2. (1) *These regulations establish the basic safety standards for the protection of the health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation.*

(2) *These regulations apply to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.*

(3) *These regulations also provide for the security of radioactive material and define specific requirements ensuring that each such source is kept under control.*

(4) *These regulations in particular apply to:*

(a) *the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from Malta of radioactive material;*

(b) *the manufacture and the operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);*

(c) *human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:*

(i) *the operation of aircraft in relation to the exposure of crews;*

(ii) *the processing of materials containing naturally-occurring radionuclides;*

(d) *the exposure of workers or members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity;*

(e) *the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.*

(5) *These regulations shall not apply to:*

(a) *exposure to the natural level of radiation, such as radionuclides contained in the human authority and cosmic radiation prevailing at ground level;*

(b) *exposure to cosmic radiation in flight by members of the public or workers other than aircrew;*

(c) *aboveground exposure to radionuclides present in the undisturbed earth's crust.*

Nuclear Safety Regulations (SL 585.02) (published 2018)
<https://legislation.mt/eli/sl/585.2>

The objectives and scope of these regulations are given in regulations 2 and 3 as:

(a) *support the European Union and international efforts to achieve and maintain a high level of nuclear safety worldwide through national measures and international co-operation;*

(b) *to ensure that national arrangements are in place to protect workers, the general public and the environment against potential radiological hazards from nuclear facilities.*

■ This regulation:(a) *shall apply to the safety of nuclear facilities;*

(b) supplements the Act and Basic Safety Standards for Ionising Radiation Regulations, as regards the nuclear safety of nuclear facilities.

Management of Radioactive Waste Regulations (SL585.03) (published 2019) <https://legislation.mt/eli/sl/585.30>

The scope of these regulations is stated as 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

The implementation of the regulatory framework of the Act and the regulations is the responsibility of the Commission.

The Secretariat of the Commission performs the executive actions. The Secretariat has developed a comprehensive management system to support its operations.

Malta is contracting party to the Convention on Nuclear safety and Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and in their review processes.

4.1 (a)

Article 4

The national framework shall provide in particular for:

1. (a) the allocation of responsibilities and coordination between relevant state bodies;

The Commission (refer to 5.1 of this document) is the sole regulator.

To aid any necessary coordination activities the Commission has signed memoranda of understandings with both the civil protection and customs entities. The Commission also has operating procedures in place with the civil protection and customs entities.

The Commission is also in talks with both the Malta Police and Maltese Secret Service in order to have memoranda of understandings with both entities.

4.1 (b), (c), (d)

Article 4

The national framework shall provide in particular for:

1. (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;

1. (c) a system of licensing and prohibition of operation of nuclear installations without a licence;

1. (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;

The Commission issues authorisations to undertakings for the use of ionising radiation pursuant to Regulation 38 of the BSS Regulations.

The management system of the Secretariat of the Commission includes procedures for the notification, review & assessment, inspection, enforcement and the licensing processes.

Article 21(1) of the Act states that failure of persons to comply with the provisions of the Act is an offence:

(1) Any person who fails to comply with the provisions of this Act, or any regulations made thereunder shall be guilty of an offence and shall be subject to the penalties established by this Act and any applicable regulations

4.1 (e)

Article 4

1. (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.

Article 19 of the Act gives the legal authority to the Secretariat of the Commission to take enforcement actions, which may include ordering the suspension of activities or suspension of the undertaking's licence.

Article 21 of the Act specifies the penalties for non compliance with provisions of the Act or regulations made under the Act.

The Secretariat of the Commission has an enforcement document within its management system which gives guidance on the appropriate enforcement action.

4.2

Article 4

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

The Commission prepares legislation in connection with ionising radiation and nuclear issues.

The drafted legislation goes through the general governmental procedures, including the required process where relevant stakeholders are consulted.

On completion of the consultation, the Commission reviews any feedback received and, based on this feedback, may revise the draft proposal. The draft is then presented to the Minister responsible for the Commission who in turn presents it to the Cabinet of Ministers for their approval.

Malta has reviewed its national framework in light of the findings of the IRRS as detailed above (given in 4.1 summary)

Malta continues to work on the findings of the 2015 IRRS mission and the IRRS follow up mission in 2020.

Article 5. Competent Regulatory Authority

5.1

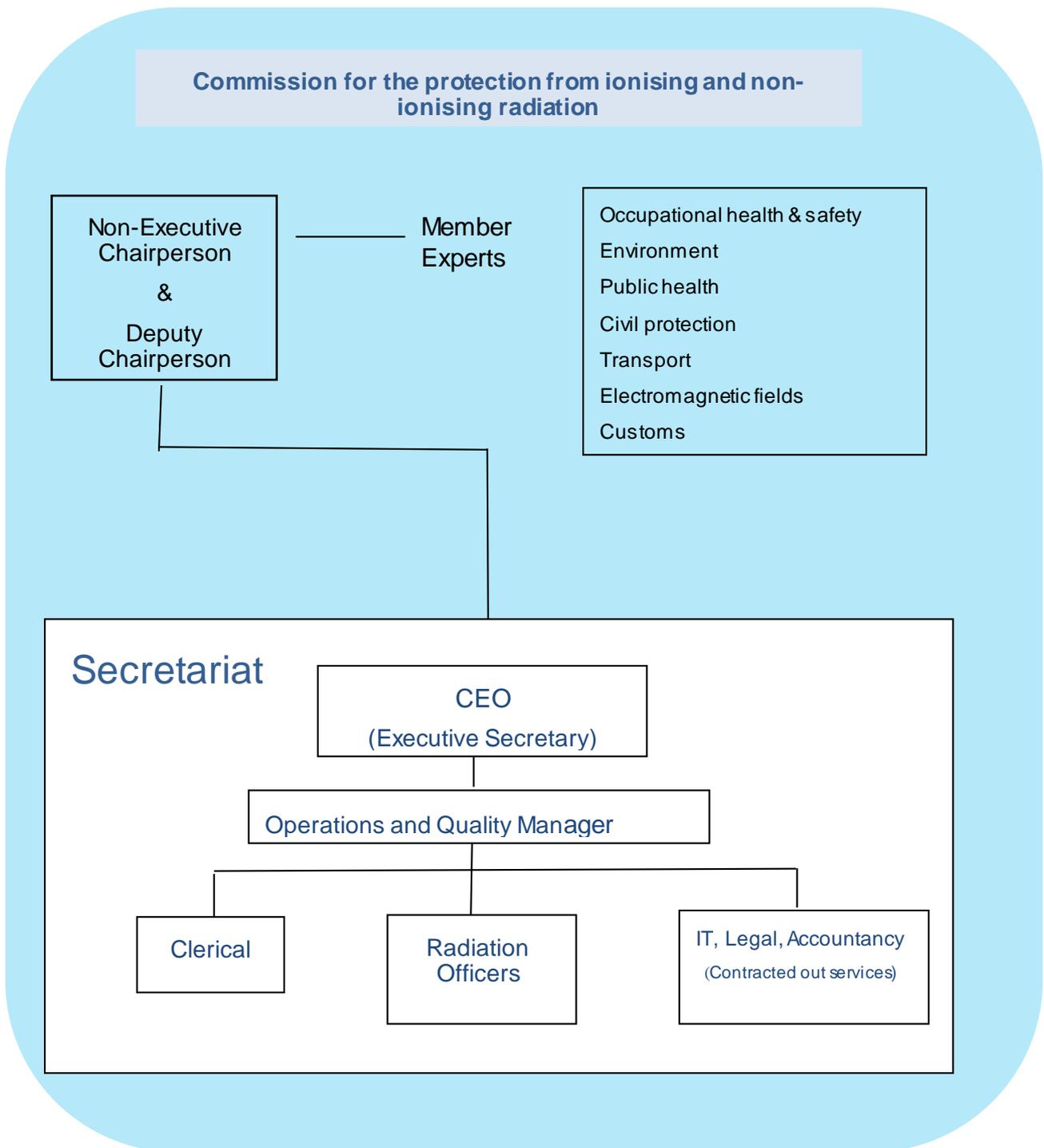
Article 5

1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.

Malta has a single regulatory authority called the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission).

The Commission is empowered by the Nuclear Safety and Radiation Protection Act (CAP 585).

The organogram of the Commission is:



5.2 (a)

Article 5

2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

(a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organisation when carrying out its regulatory tasks;

The Act has provisions for the creation of the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission) as an independent regulatory authority that has functional separation from entities having responsibilities or interests that could unduly influence its decisions.

The members of the Commission were first appointed in October 2018 and were recently, reappointed by the Minister in July 2020.

The Act refers to the Minister as:

“Minister” means the Minister responsible for matters related to and incidental to this Act and such Minister shall not have under his responsibility any form of ionising or non-ionising radiation facility or source;

Article 10(5) of the Act states that it is the Minister who appoints the members of the Commission and this Article states that no members shall be responsible for the use of any form of ionising radiation.

(5) The Minister shall appoint members, as expert members in the Commission, for a period of three years and such period may be extended for further periods of three years each. The Commission shall be composed as follows:

- (a) one member with regard to occupational health and safety issues*
- (b) one member with regard to environment issues;*
- (c) one member with regard to the public health issues;*
- (d) one member with regard to the civil protection issues;*
- (e) one member with regard to transportation issues;*
- (f) one member with regard to the electromagnetic field issues;*
- (g) one member with regard to customs issues;*
- (h) one member representing civil society; and*
- (i) one member representing the field of communications:*

Provided that the Minister may change the composition of the Commission so as to reflect the regulatory exigencies developing from time to

time, provided that no members shall be responsible for the use of any form of ionising or non-ionising radiation.

Members of the Commission shall be allowed to be represented by a replacement at meetings of the Commission and any such replacements shall have voting rights.

The Executive Secretary shall attend all meetings of the Commission but shall not have voting rights.

Article 10(6) of the Act states it is for the Minister to appoint the Chairperson and the Deputy Chairperson

(6) The Chairperson and the Deputy Chairperson shall be appointed by the Minister for a period of three years and such period may be extended for further periods of three years each:

Provided that where the Chairperson is absent from Malta or is otherwise temporarily unable to perform the functions of that office, all duties and functions of the Chairperson shall be assumed by the Deputy Chairperson.

The Commission is effectively independent of the regulatory decision making as it is functionally separate from the bodies responsible for promotion or utilisation of ionising radiation or electricity production.

5.2 (b)

Article 5

2. (b) takes regulatory decisions founded on robust and transparent nuclear safety-related requirements;

Whenever regulatory decisions have to be made, the Commission ensures that such decisions are based on the relevant safety requirements. This is ensured that such safety requirements are enacted in new or revised legislation. The Commission does so by taking into account EU directives or regulations and international safety standards, notably the IAEA's safety standards.

Any such regulatory decision is based on the current legislation, which in turn is based on the current safety standards, thus ensuring transparency of such decisions.

5.2 (c)

Article 5

2. (c) is given dedicated and appropriate budget allocations to allow for the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget;

Financial independence is guaranteed by Article 61 of the Act:

61. (1) *The Commission and the Secretariat shall be provided with adequate financial and human resources, through the national budget, to fulfil their responsibilities under this Act and applicable regulations.*

(2) *The Commission may charge fees pursuant to article 10(2)(g):*

Provided that any fees or fines collected by the Secretariat shall be paid to the Ministry for Finance.

(3) *The Minister responsible for Finance may, after consultation with the Minister, make advances to the Commission of such sums as the Minister responsible for Finance may agree to be required by the Commission for carrying out any of its functions under this Act, and may make such advances on such terms and conditions as the Minister responsible for Finance may, after consultation as aforesaid, deem appropriate. Any such advance may be made by the Minister responsible for Finance out of the Consolidated Fund, and without further appropriation other than this Act, by warrant, authorising the Accountant General to make such advance.*

(4) *The Commission shall be responsible for developing its own budget and for presenting it to the Minister for approval.*

(5) *The Commission shall cause to be prepared, at the end of every financial year, a financial report recording the income and expenditure of the Commission and the Secretariat and the projected estimates of the income and expenditure of Commission and the Secretariat for the next following financial year: Provided that the estimates of the Commission for the first financial year of the Commission shall be prepared and adopted within such time as Minister may, by notice in writing to the Commission, specify.*

The Commission has a dedicated budget through separate line vote in the Ministry's Budget which it has the responsibility to manage for the functioning of the regulatory authority.

5.2 (d)

Article 5

2. (d) employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;

Commission provides the Ministry with a three-year human resource plan every year.

The current compliment in the Secretariat of the Commission is of two full time staff. The recruitment process for three additional technical staff is currently ongoing.

Currently no other technical expertise to support the regulatory functions is being sought, however the Commission may do so whenever necessary.

5.2 (e)

Article 5

2. (e) establishes procedures for the prevention and resolution of any conflicts of interest;

The Act created the Commission as an effectively independent regulatory body that has functional separation from entities having responsibilities or interests that could unduly influence its decision-making.

The Act stipulates that the Minister responsible for the Commission shall not have under his responsibility any form of ionising or non-ionising radiation facility or source.

The Act stipulates that the expert members of the Commission shall not be responsible for the use of any form of ionising or non-ionising radiation.

5.2 (f)

Article 5

2. (f) provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.

The Commission does not require any clearances from any organisation prior to presenting recommendations to the Minister responsible for the Commission.

In view that Malta has no nuclear facility (installation), the only nuclear safety related information that will be relevant for Malta is in relation to issues related to overseas nuclear facilities. Regulation 7 of Nuclear Safety Regulations (SL 585.02)

Insofar as that Malta is likely to be affected by a nuclear or radiological emergency and pursuant to regulations 93 and 94 of BSS Regulations the Secretariat and if appropriate the Civil Protection Department shall ensure that the Maltese population are provided with appropriate information for emergency planning and response. The only nuclear safety related information that will be relevant for Malta is in relation to issues related to overseas nuclear facilities.

The Commission is in regular contact with its Ministry and is required by Article 11(6) of the Act to provide an annual report to the Ministry.

5.3 (a)

Article 5

3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:

(a) propose, define or participate in the definition of national nuclear safety requirements;

The Commission is empowered by Article 10(2) of the Act to:

(a) draw up and establish policies and strategies in consultation with the Minister to be followed by the Secretariat, relating to the protection against ionising and non-ionising radiation and other concerns addressed by the Act;

(b) co-ordinate the preparation of regulations governing any issues made in connection with this Act;

5.3 (b)

Article 5

3. (b) require that the licence holder complies and demonstrates compliance with national nuclear safety requirements ;

Article 21 of the Act states that any person who fails to comply with the provisions of the Act or any regulations made under the Act shall be guilty of an offence.

5.3 (c)

Article 5

3. (c) verify such compliance through regulatory assessments and inspections;

Under Article 12 of the Act the Secretariat shall inspect and assess activities to verify compliance with the Act and regulations made under the Act.

5.3 (d)

Article 5

3. (d) propose or carry out effective and proportionate enforcement actions.

The Secretariat to has enforcement powers given to it by virtue of Article 19 of the Act.

Article 21 of the Act specifies the penalties.

Article 6. License Holder

6.1 (a)

Article 6

1. (a) the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;

Article 5 of the Act and regulation 5(3) of the BSS Regulations state:

The prime responsibility for the safety and security of ionising and non-ionising radiation sources rests with the undertaking:

Provided that the prime responsibility for safety and security rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might effect safety and security.

6.1 (b)

Article 6

1. (b) when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;

Regulation 38 of the BSS regulations details the information required when requesting an authorisation.

6.1 (c)

Article 6

1. (c) licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner. That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions;

Undertakings are required, by regulation 70 of the BSS regulations, as part of their radiation protection programme to have procedures for:

methods for periodically reviewing and auditing the performance of the radiation protection programme.

6.1 (d)

Article 6

1. (d) licence holders establish and implement management systems which give due priority to nuclear safety;

Undertaking are required to have radiation protection programmes in place by virtue of regulation 100 of the BSS regulations.

6.1 (e)

Article 6

1. (e) licence holders provide for appropriate on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences. Those shall in particular:

- (i) be consistent with other operational procedures and periodically exercised to verify their practicability;
- (ii) address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units;
- (iii) provide arrangements to receive external assistance;
- (iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;

Article 30 of the Act states:

No licence to conduct an activity or practice, operate a facility, or possess or use a source may be granted unless and until an appropriate emergency

preparedness and response plan has been developed by the applicant and reviewed by the Secretariat.

Regulation 90 of the BSS Regulations states:

90. (1) *Undertakings are to notify either the Secretariat or the Civil Protection Department immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences.*

(2) *Undertakings shall make an initial provisional assessment of the circumstances and consequences of the emergency and assist with protective measures.*

(3) *Undertakings shall ensure that provision is made for protective measures with regard to:*

(a) *the radiation source, to reduce or stop the radiation, including the release of radionuclides;*

(b) *the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways;*

(c) *individuals, to reduce their exposure.*

The Tenth Schedule of the BSS regulations gives details of the elements to be included in emergency management systems and emergency response plans.

Regulation 70(f)(xiv) and 100(2)(e) of the BSS Regulations requires the undertaking to review and audit its radiation protection programme.

6.1 (f)

Article 6

1. (f) licence holders provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competences to fulfil their obligations.

Malta does not have any nuclear installation license holders.

Article 7. Expertise and Skills in Nuclear Safety

Article 7

Member States shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to

obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness.

Article 25 of the Act requires that undertakings ensure that their workers are adequately trained. Further requirements for training are included in regulations 14-18 of the BSS regulations.

The Secretariat has procedures in place for initial and on-going staff training.

Article 8. Information to the Public

Article 8:
Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. 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.

The Commission does not currently have a website for provision of information to the public.

The Regulatory Requirements

The Act allows the Commission to publish orders given to undertakings, Article 20(5) states:

(5) Where any officer of the Secretariat makes an order in writing under this article, or issues a report of inspection to an undertaking or to a person in charge of work, the undertaking or person in charge of work shall forthwith cause a copy or copies thereof to be posted in a conspicuous place or places at the practice or activity where it is most likely to come to the attention of workers:

Provided that it shall also be at the discretion of the Secretariat, with the concurrence of the Commission, to publish such order in the Gazette, if it is such to safeguard the public interest.

In connection with the management of existing exposure situations BSS Regulation 126(1) requires stakeholders to be involved in decisions:

126. (1) The Commission shall advise the Minister on the assignment of responsibilities for the implementation of strategies for the management of existing exposure situations, and ensure appropriate coordination between relevant parties 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.

In connection with the management of existing exposure situations BSS Regulation 126(4) requires information and guidance to be provided by the Commission to populations in connection with potential exposure situations.

(4) *In the implementation of a strategy the Commission shall regularly:*

(a) evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;

(b) provide information to exposed populations on the potential health risks and on the available means for reducing their exposure;

(c) provide guidance for the management of exposures at individual or local level;

(d) with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, provide information on appropriate means for monitoring concentrations and exposures and for taking protective measures.

BSS Regulations 93 and 94 requires the Commission to provide information in emergency situations

93 *(1) Secretariat shall ensure that the members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.*

(2) The information supplied shall include at least the elements set out in Section A of the Eleventh Schedule

(3) The information shall be communicated to the members of the public referred to in sub-regulation (1) without any request being made.

(4) The Commission shall ensure that the information is updated and distributed at regular intervals and whenever significant changes take place. This information shall be permanently available to the public.

94. *(1) The Secretariat and Civil Protection Department shall ensure that, when an emergency occurs, the members of the public actually affected are informed without delay about the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.*

(2) The information provided shall cover those paragraphs listed in Section B of the Eleventh Schedule which are relevant to the type of emergency."

Management System

Development of documentation that warrants input from stakeholders is dealt with management system procedures.

Within the management system several procedures make reference to posting information on the Commission web-site. The Commission website has not yet been developed, so currently information can be posted on the Ministry website.

Article 8a. Nuclear Safety Objective for Nuclear Installations

Article 8a

1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

- (a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;
- (b) large radioactive releases that would require protective measures that could not be limited in area or time.

2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:

- (a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;
- (b) is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

There are no nuclear installations in Malta.

Article 8b. Implementation of the Nuclear Safety Objective for Nuclear Installations

Article 8b

1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:

- (a) the impact of extreme external natural and unintended man-made hazards is minimised;
- (b) abnormal operation and failures are prevented;
- (c) abnormal operation is controlled and failures are detected;
- (d) accidents within the design basis are controlled;
- (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;
- (f) organisational structures according to Article 8d(1) are in place.

2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to

promote and enhance an effective nuclear safety culture. Those measures include in particular:

- (a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(d);
- (b) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;
- (c) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority; and, Article 8b
- (d) arrangements for education and training, in accordance with Article 7.

There are no nuclear installations in Malta.

Article 8c. Initial Assessment and Periodic Safety Reviews

Article 8c

Member States shall ensure that the national framework requires that:

- (a) any grant of a licence to construct a nuclear installation or operate a nuclear installation, is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a;

Member States shall ensure that the national framework requires that:

- (b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.

There are no nuclear installations in Malta.

Article 8d. On-site Emergency Preparedness and Response

8d.1

Article 8d

1. Without prejudice to the provisions of the Directive 2013/59/Euratom, Member States shall ensure that the national framework requires that an organisational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the licence holder, and competent authorities and organisations, taking into account all phases of an emergency.

The BSS regulations includes regulatory requirements for, the notification of an incident/accident, initial assessment of an emergency situation, taking

mitigatory actions, assisting the response organizations with protective actions and public information.

Generic information on establishing emergency response plans and their content is provided in the Tenth Schedule of the BSS regulations

8d.2

Article 8d

2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom

Article 31 of the Act requires that the Secretariat maintains a national radiological emergency plan. Article 31 states:

A national emergency plan for responding to potential nuclear or radiological emergencies shall be developed and maintained by the Secretariat in conjunction with the Commission and approved by the Minister, after consultation with the Commission and other Ministers, if the Minister believes that their consultation is necessary to fulfil his functions under this Act.

Malta has a national radiological emergency plan. The emergency plan was completed following a radiological emergency threat assessment (using IAEA methodology).

The scope of the threat assessment document is to identify the radiological threats in the event of an incident that would require the radiological emergency procedures to be activated.

The scope of the radiological emergency plan document is to:

- Provide a framework for the operation of the activities by government entities to mitigate the effects of the risks identified in threat assessment document
- Outline the government entities likely to be involved and their responsibilities.
- Place responsibilities on each government agency involved in the plan to develop its own procedures

Resources Available for Emergency Response

The Civil Protection Department is fully equipped with field equipment and has undergone both initial training in radiological response with the assistance of the IAEA and also has undergone further training in this area as part of the national radiological, biological chemical response plan.

Article 8e. Peer Reviews

Article 8e

1. Member States shall, at least once every 10 years, arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of such peer reviews shall be reported to the Member States and the Commission, when available.

Malta was subject to an IRRS Mission in 2015, with the follow-up mission in March 2020, the end of mission report https://www.iaea.org/sites/default/files/documents/review-missions/irrs_report_malta_26may2015.pdf made a series of recommendations, including several on the regulatory infrastructure.

The IRRS follow-up mission report <https://www.iaea.org/services/review-missions/calendar?type=3158&year%5Bvalue%5D%5Byear%5D=&location=All&status=4275> acknowledge the progress made.