

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 20,400, 5 ta' Mejju, 2020

Taqsimha B

L.N. 184 of 2020

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

**Basic Safety Standards for Ionising Radiation
(Amendment) Regulations, 2020**

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

1. The title of these regulations is the Basic Safety Standards for Ionising Radiation (Amendment) Regulations, 2020, 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. Immediately after the definition "sievert" in regulation 4 of the principal regulations there shall be added the following:

Amends
regulation 4 of
the principal
regulations.

" "spacecraft" means a manned vehicle designed to operate at an altitude of more than 100 km above sea level;"

3. Regulation 6 of the principal regulations shall be substituted by the following:

Substitutes
regulation 6 of
the principal
regulations.

"6. Dose constraints for the purpose of prospective optimisation of protection shall be:

(1) (a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking and shall be one third of any dose limits specified in regulations 9,10 and 11. In the case of outside workers the dose constraint shall be established in cooperation between the employer of the outside worker and the undertaking;

(b) for public exposure, the dose constraint shall be 0.25mSv per year for the individual dose that members of the public receive from the planned operation of a specified radiation source;

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(c) for medical exposure, dose constraints shall apply only with regard to the protection of carers and comforters, which shall be 1.5mSv per five years pursuant to regulation 66(6a) and volunteers participating in medical or biomedical research pursuant to regulation 66(4c).

(2) In the event that any dose constraint is exceeded the undertaking is to immediately inform the Commission and then produce a report detailing the event and doses received."

Amends
regulation 7 of
the principal
regulations.

4. Immediately after sub-regulation (3)(b) of regulation 7 of the principal regulations there shall be added the following:

"(c) in the range up to or equal to 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures."

Substitutes
regulation 8 of
the principal
regulations.

5. Regulation 8 of the principal regulations shall be substituted by the following:

"8. (1) Persons under 18 years of age may not be assigned to any work which would result in them as being classed as an exposed worker subject to regulation 11(2).

(2) No person under 16 years of age shall be allowed to be subject to any form of occupational exposure."

Amends
regulation 10 of
the principal
regulations.

6. Regulation 10(1) of the principal regulations shall be substituted by the following:

"(1) As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer of the outside worker, of the pregnancy, in accordance with regulation 3 of Protection of Maternity at Work Places Regulations, the undertaking, and the employer of the outside worker, shall ensure that the employment conditions for the pregnant worker are such that the protection of the unborn child is comparable with that provided for members of the public and the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1mSv during at least the remainder of the pregnancy."

S.L. 424.11

Adds new
regulations to
the principal
regulations.

7. Immediately after regulation 14 of the principal regulations

there shall be added the following:

"Courses in medical and dental schools.

14A. The Commission shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

Exposed workers to provide information.

14B. Exposed workers shall make available to the undertaking or the employer of the outside worker information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others."

8. Regulation 17(1) of the principal regulations shall be substituted by the following:

Amends regulation 17 of the principal regulations.

" (1) Emergency workers who are identified in an emergency response plan of an undertaking or the employer of an outside worker and persons involved in the national radiological emergency plan as established by article 31 of the Act, shall be given adequate information:

(a) that is regularly updated on the health risks their intervention might involve and on the precautionary measures to be taken in such an event;

(b) on appropriate radiation protection training;

(c) on national radiological emergency plan as set out in regulation 122:

Provided that this information shall take into account the range of potential emergencies and the type of intervention."

9. Immediately after regulation 21 of the principal regulations there shall be added the following:

Adds a new regulation to the principal regulations.

"Resources.

21A. The Commission shall allocate the necessary resources in order that staff of its Secretariat to obtain, maintain and further develop expertise and skills required in discharging the Commission's responsibilities."

10. Regulation 32 of the principal regulations shall be substituted by the following:

Substitutes regulation 32 of the principal regulations.

"32. (1) Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

(2) Regulatory control through the notification, registration/ licensing and the inspection process shall use a graded approach."

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Adds new regulations to the principal regulations.

11. Immediately after regulation 32 of the principal regulations there shall be added the following:

"Registers.

32A. The Secretariat shall be responsible for maintaining a registers of:

- (1) undertakings and employers of outside workers;
- (2) equipment that requires notification under these regulations;

(3) radioactive material that requires notification under these regulations, and in particular the following information:

- (a) radionuclide involved;
- (b) the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market; and
- (c) the type of source.

(4) Transfers of equipment and radioactive material that requires notification under these regulations."

Amends regulation 48 of the principal regulations.

12. Regulation 48(4) of the principal regulations shall be substituted by the following:

"(4) Monitoring equipment used for radiological surveillance of the workplace shall be annually recalibrated and the calibration shall be traceable to an accredited standards laboratory."

Amends regulation 62 of the principal regulations.

13 Immediately regulation 62(2) of the principal regulations there shall be added the following:

"(3) The Secretariat shall be informed if the exposure of spacecraft crew is likely to exceed dose limits and shall ensure that it is managed as a specially authorised exposure."

Amends regulation 64 of the principal regulations.

14. Regulation 64(3) of the principal regulations shall be substituted the following:

"(3) In areas within workplaces, where the radon concentration (as an annual average), continues to exceed the national reference level, despite the action taken in accordance with the principle of optimisation as set out in Part III and taking into account parameters contained in the national action plan as under point 2 of the Sixteenth Schedule notification in accordance with regulations 34(4) and 44(2) shall apply."

Amends regulation 65 of the principal regulations.

15. Regulation 65 of the principal regulations shall be amended as follows:

(a) sub-regulation (2)(g) thereof shall be substituted the following:

"(g) Undertakings shall obtain clearance from the Commission before any type of health screening is performed. The Commission shall seek advice from any appropriate medical scientific societies and health regulatory bodies and shall make reference to any available internationally accepted justification norms for screening." and

(b) immediately after sub-regulation (2) thereof, there shall be added the following:

"(3) Referrers shall as part of the justification process:

(a) ensure and document that the medical exposure of the patient is warranted based on the medical indications;

(b) make reference to referral criteria;

(c) refer the patient to a practitioner, providing adequate clinical details;

(d) state on each individual referral the clinical question to be answered;

(e) where practical, seek, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure; and

(f) seek the outcome of the exposure and act on the result."

16. Sub-regulation (2)(f) of regulation 65 of the principal regulations shall be substituted the following:

Amends
regulation 65 of
the principal
regulations.

"(f) For the justification of any medical exposure for medical or biomedical research undertakings shall obtain clearance from the Commission. Prior to the Commission issuing clearance for any medical exposure for medical or biomedical research the undertakings shall provide confirmation that they have obtained clearance from the ethics committee."

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Amends
regulation 66 of
the principal
regulations.

17. Regulation 66(3) of the principal regulations shall be substituted the following:

"(3) The Commission shall establish and regular review their use of 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."

Amends
regulation 71 of
the principal
regulations.

18. Regulation 71(1) of the principal regulations shall be substituted the following:

"(1) The Commission shall set the training and recognition requirements, as laid down in regulations 102 and 14, for the practitioner, the medical physics expert and the individuals referred to in regulation 69."

Substitutes
regulation 72 of
the principal
regulations.

19. Regulation 72 of the principal regulations shall be substituted the following:

"72. (1) The responsibility to ensure that the equipment is fit for clinical use resides with the undertaking.

(2) Prior to acquiring medical radiological equipment the undertaking shall ensure that there is adequate information on the radiological risks for patients, and on the clinical evaluation of the its use."

Substitutes
regulation 76 of
the principal
regulations.

20. Regulation 76 of the principal regulations shall be substituted by the following:

"76. The calibration of equipment used for dosimetry of patients and acceptance or constancy testing shall be traceable to an accredited standards dosimetry laboratory and shall be routinely re-calibrated according to its instructions for use. In the absence of any specified dosimeter re-calibration period, the equipment calibration period must not exceed a period of two years."

Amends
regulation 79 of
the principal
regulations.

21. Sub-regulation (1)(d) of regulation 79 of the principal regulations shall be substituted the following:

"(d) When radiological equipment is not being used it must be left in a safe and secure condition and when it is in use it must be kept under strict surveillance regarding radiation protection."

22. Regulation 89(2) of the principal regulations shall be substituted the following:

Amends regulation 89 of the principal regulations.

"(2) The national radiological protection plan shall be developed following a national radiological hazard assessment that shall be performed by the Commission."

23. Regulation 91 of the principal regulations shall be substituted by the following:

Substitutes regulation 91 of the principal regulations.

"Emergencies on or outside Maltese territory.

"91. (1) In the event of an emergency on or outside Maltese territory, the Commission shall:

(a) work with the civil protection authorities to organise the appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the national radiological emergency plan referred to in regulation 89, whereby the elements to be included in an emergency response plan are indicated in Section B of the Tenth Schedule;

(b) coordinate the recovery of any radioactive material;

(c) advice on the termination of nuclear or radiological emergency and the transition to normal activities;

(d) assess and record the consequences of the emergency and of the effectiveness of the protective measures.

(2) Undertakings shall have appropriate emergency preparedness and response procedures in place as indicated in the Tenth Schedule."

24. Immediately after regulation 100(3) of the principal regulations there shall be added the following:

Amends regulation 100 of the principal regulations.

"(4) Undertakings shall record any report received from a worker that identifies any radiological safety concerns or and shall take appropriate action"

25. Regulation 101(1) of the principal regulations shall be substituted the following:

Amends regulation 101 of the principal regulations.

"(1) It is the responsibility of the undertaking to ensure that appropriate safety assessment/s are performed. The safety assessment shall:

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(a) identify ways in which potential exposures or accidental and unintended medical exposures could occur;

(b) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;

(c) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;

(d) define the operational limits and conditions of operation."

Amends
regulation 105
of the principal
regulations.

26. Immediately after regulation 105(4) of the principal regulations there shall be added the following:

"(5) Where a radiation protection expert is consulted pursuant to the requirements of these regulations the undertaking shall appoint that radiation protection expert in writing and shall include in that appointment the scope of the advice which the radiation protection expert is required to give."

Substitutes
regulation 114
of the principal
regulations.

27. Regulation 114 of the principal regulations shall be substituted by the following:

"114. (1) Undertakings shall obtain a prior license from the Secretariat for any practice involving a high activity source, including taking possession of a source.

(2) The Commission shall require that adequate provision, by way of a financial security or any other equivalent means appropriate to the source in question, having been made for the safe management of sources when they become disused sources, including the case where the holder becomes insolvent or goes out of business

(3) Undertakings are required, that in addition to the general licensing requirements set out in Part V, shall have provided for, within its radiation protection programme for:

(a) the safe and secure management of sources;

(b) disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, another licensee;

(c) assignment of responsibilities within the undertaking;

(d) provision of minimum staff competencies, including information and training;

(e) obtaining the minimum source, source container and additional equipment performance criteria;

(f) emergency procedures and communication links;

(g) work procedures to be followed;

(h) maintenance of equipment, sources and containers;

(i) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, another authorised holder or a recognised installation;

(j) developed a security plan or assessment including measures to detect and delay the unauthorised access to, or the theft, loss or unauthorised use or removal of radioactive sources during all stages of management. The degree of security required, shall be dependent on the security level as laid out in the three columns of Table 1 of the Second Schedule. Security measures for the different security levels are given in Table 1 in the Fourteenth Schedule. The security plan or assessment shall be periodically reviewed and records of such reviews kept;

(k) minimum performance criteria and maintenance requirements for equipment and systems used to ensure the safety and security of radioactive sources;

(l) measures to determine, as appropriate, the trustworthiness of individuals involved in the management of radioactive sources; and

(m) the confidentiality of information relating to the security of sources.

(4) Each undertaking in possession of high activity sealed sources shall:

(a) ensure that suitable tests, such as leak tests based on international standards, are undertaken every 14 months in order to check and maintain the integrity of each source;

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(b) carry out verification that each source and, where relevant, the equipment containing the source, is still present and in apparently good condition at its place of use or of storage. Verification frequency shall be as listed in Table 1 in the Fourteenth Schedule;

(c) ensure that each fixed and mobile source is subject to adequate documented measures, such as written protocols and procedures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire;

(d) promptly notify the Secretariat of any loss, leakage, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, including fire, that may have damaged the source and, if appropriate, inform the Board thereof and of the measures taken;

(e) return each disused source to the supplier or place it in a facility for long term storage or disposal or transfer it to another authorised undertaking unless otherwise agreed by the Commission, without undue delay after termination of the use;

(f) ascertain that, before a transfer is made, the recipient holds appropriate license;

(g) promptly notify the Secretariat of any incident or accident resulting in unintentional exposure of a worker or a member of the public.

(5) Each undertaking in possession of high activity sealed sources shall in connection for training and information ensure:

(a) includes specific requirements for the safety and security of the management of sources;

(b) contain specific information on possible consequences of the loss of adequate control of sources;

(c) repeated at regular intervals and documented, with a view to preparing the relevant workers adequately for such events, be addressed to exposed workers."

Amends
regulation 122
of the principal
regulations.

28. Regulation 122(2) of the principal regulations shall be substituted by the following:

"(2) The national radiological emergency plan shall take

into account the risks identified in the national radiological hazard assessment performed by the Commission."

29. Immediately after point (b) of 2ii of the Fourth Schedule the principal regulations there shall be added the following:

Amends the Fourth Schedule to the principal regulations.

"(c) Use of ionising radiation for detection of concealed objects on or attached to the human body."

30. Immediately after point (6) of Part A of the Tenth Schedule the principal regulations there shall be added the following:

Amends the Tenth Schedule to the principal regulations.

"(7) Arrangements for individual monitoring or assessment of individual doses of emergency workers and the recording of doses;

(8) Public information arrangements;

(9) Involvement of stakeholders;

(10) Transition from an emergency exposure situation to an existing exposure situation including recovery and remediation."

31. Immediately after point (3) of Part A of the Eleventh Schedule of the principal regulations there shall be added the following

Amends the Eleventh Schedule to the principal regulations.

"(4) Appropriate information on action to be taken by the public in the event of an emergency."

32. The table in Part 2 of the Seventeenth Schedule of the principal regulations shall be substituted the following:

Amends the Seventeenth Schedule to the principal regulations.

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Qualification	Medical doctors who are on the Specialist Registers held by the Medical Council for: Radiology; Radiotherapy; Nuclear Medicine,
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	or Medical doctors who are on the Specialist Register held by the Medical Council for: Cardiology; Gastroenterology; Respiratory Medicine; Rheumatology; Orthopedic Surgery; and General Surgery Oral and maxillo-facial surgery while carrying out interventions,
	or Dental surgeons,
	or Medical radiographers registered with Council for Professions complimentary to medicine
Experience	At least one month on the job experience under the supervision of an approved practitioner, excluding dental surgeons. No initial experience for dental work performed by dental surgeons.

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