SUBSIDIARY LEGISLATION 585.01

BASIC SAFETY STANDARDS FOR IONISING RADIATION REGULATIONS

6th February, 2018

LEGAL NOTICE 210 of 2018, as amended by Legal Notice 184 of 2020.

Arrangement of Regulations

Part V
JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

(SECTION 1)
Justification and prohibition of practices

(SECTION 2)
REGULATORY CONTROL

Part VI
OCCUPATIONAL EXPOSURES

Part I

General Provisions

Citation.

1. (1) The title of these regulations is the Basic Safety Standards for Ionising Radiation Regulations.

(2) These regulations implement Directive 2013/59/ Euratom, Basic Safety Standards for Protection Against the Dangers Arising From Exposure to Ionising Radiation.

Subject matter and scope.

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 body 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.

Enforcement.

3. The Commission shall have the power to enforce these regulations.

Part II

Definitions

Interpretation. Amended by: L.N. 184 of 2020.

4. In these regulations, unless the context otherwise requires:

"acceptance test" means is a test to check the compliance of equipment, used in connection with medical exposure, with specified tolerances;

"accident" shall mean any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of radiation protection or safety;

Cap. 585.

"Act" means the Nuclear Safety and Radiation Protection Act;

"absorbed dose" (D) means the energy absorbed per unit mass

$$D = \frac{d\,\overline{\epsilon}}{dm}$$

Where

$d\,\overline{\epsilon}$ is the mean energy imparted by ionizing radiation to the matter in a volume element, dm is the mass of the matter in this volume element.

In these regulations, absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray (Gy) where one gray is equal to one joule per kilogram;

"accelerator" means equipment or installation, in which

particles are accelerated, emitting ionizing radiation with an energy higher than 1 mega-electron volt (MeV);

"accidental exposure" means an exposure of individuals, other than emergency workers, as a result of an accident;

"activation" means a process through which a stable nuclide is transformed into a radionuclide by irradiating with particles or high-energy photons the material in which it is contained;

"activity" (A) is the activity of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of dN by dt, where dN is the expectation value of the number of nuclear transitions from that energy state in the time interval dt:

$$A = \frac{dN}{dt}$$

The unit of activity is the Becquerel (Bq);

"apprentice" means a person receiving training or instruction within an undertaking with a view to exercising a specific skill;

"applicant" means a legal person who applies to Secretariat filing a application to the Secretariat for the purpose of obtaining the authorisation for undertaking of specific activities;

"authorisation" means a permission granted in a document by the Secretariat to carry out a practice or any other action within the scope of these regulations. Authorisations can take the form of a registration or a licence.

"becquerel" (Bq) is the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second;

"building material" means any construction product for incorporation in a permanent manner in a building or parts thereof and the performance of which has an effect on the performance of the building with regard to exposure of its occupants to ionising radiation;

"carers and comforters" means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;

"clearance levels" means values, established by the Commission, and expressed in terms of activity concentrations at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of these regulations;

"clinical audit" means a systematic examination or review of

medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary;

"clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;

"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;

"committed effective dose" ($E(\tau)$) is the sum of the committed organ or tissue equivalent doses $H_T(\tau)$ resulting from an intake, each multiplied by the appropriate tissue weighting factor w_T. It is defined by:

$$E(\tau) = \sum_T w_T H_T(\tau)$$

In specifying $E(\tau)$, is given in the number of years over which the integration is made. For the purpose of complying with dose limits specified in these regulations, is a period of 50 years following intake for adults and up to the age of 70 for infants and children. The unit for committed effective dose is the sievert (Sv);

"committed equivalent dose" ($H_T(\tau)$) is the integral over time (t) of the equivalent dose rate in tissue or organ T that will be received by an individual as a result of an intake.

It is given by:

$$H_T(\tau) = \int_{t_{o-}}^{t_0+\tau} \dot{H}_T\,(t)dt$$

for an intake at time t_0 where

$\dot{H}_{T\,(t)}$ is the relevant equivalent dose rate in organ or tissue T at

time t,

τ is the time over which the integration is performed.

In specifying HT(τ), is given in number of years over which the integration is made. For the purpose of complying with dose limits specified in these regulations, τ is a period of 50 years for adults and up to the age of 70 for infants and children. The unit for committed equivalent dose is the sievert (Sv);

"consumer product" means a device or manufactured item into which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale;

"constancy test" means a test intended to monitor the constancy of the functional performance of the equipment used in connection with medical exposures;

"contamination" means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body;

"controlled area" means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled;

"diagnostic reference levels" means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment;

"disused source" means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted but continues to require safe management;

"dose constraint" means a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation;

"dose limit" means the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual;

"dosimetry service" means a body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure radioactivity in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognised by the Commission;

"effective dose" (E) is the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external exposure. It is defined by the expression:

$$E = \sum_T W_T H_T = \sum_T W_T \sum_R W_R D_{T,R}$$

Where

$D_{T,R}$ is the absorbed dose averaged over tissue or organ T, due to radiation R,

W_R is the radiation weighting factor and

W_T is the tissue weighting factor for tissue or organ T

H_T is the equivalent dose absorbed by tissue T

The values for W_T and W_R are specified in the First Schedule. The unit for effective dose is the sievert (Sv);

"emergency" means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences;

"emergency exposure situation" means a situation of exposure due to an emergency;

"emergency management system" means the elements listed in Section A of the Tenth Schedule, as incorporated in the national radiological emergency plan, for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation;

"emergency occupational exposure" means exposure received in an emergency exposure situation by an emergency worker;

"emergency response plan" means those elements listed in Section B of the Tenth Schedule to plan for adequate response in the event of an emergency exposure situation on the basis of postulated events and related scenarios;

"emergency worker" means any person having a defined role in an emergency and who might be exposed to radiation while taking action in response to the emergency;

"environmental monitoring" means the measurement of external dose rates due to radioactive substances in the environment or of concentrations of radionuclides in environmental media;

"equivalent dose" (HT) is the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

$$H_{T,R} = W_R D_{T,R}$$

where

$D_{T,R}$ is the absorbed dose averaged over tissue or organ T, due to radiation R,

W_R is the radiation weighting factor.

When the radiation field is composed of types and energies with different values of W_R, the total equivalent dose, H_T, is given by:

$$H_T = \sum_R W_R D_{T,R}$$

The values for W_R are specified in Section A of the First The unit for equivalent dose is the sievert (Sv);

"exemption level" means a value established the Commission and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation;

"existing exposure situation" means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;

"exposed worker" means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by these regulations and who is liable to receive doses exceeding any one of the dose limits for public exposure;

"exposure" means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure);

"extremities" means the hands, forearms, feet and ankles;

"graded approach" means a structured method by which the

stringency of control to be applied to a product or process is commensurate with the risk;

"health detriment" means reduction in length and quality of life occurring in a population following exposure, including those arising from tissue reactions, cancer and severe genetic disorder;

"health screening" means a procedure using medical radiological installations for early diagnosis in population groups at risk;

"high-activity sealed source" means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value laid down in the fourth column of the table of the Second Schedule;

"individual detriment" means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;

"inspection" means an investigation by the Secretariat to verify regulatory compliance;

"intake" means the total activity of a radionuclide entering the body from the external environment;

"interventional radiology" means the use of X-ray imaging techniques to facilitate the introduction and guidance of devices in the body for diagnostic or treatment purposes;

"ionising radiation" means energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} hertz or more) capable of producing ions directly or indirectly;

"licence" means permission granted in a document by the Secretariat to carry out a practice in accordance with specific conditions laid down in that document;

"medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;

"medical physics expert" means an individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the Commission;

Cap. 464. "medical radiographer" shall have the meaning ascribed by radiographer under the Health Care Professions Act;

"medical radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;

"medical radiological installation" means a facility where medical radiological procedures are performed;

"medical radiological procedure" means any procedure giving rise to medical exposure;

"members of the public" means individuals who may be subject to public exposure;

"Minister" means the minister responsible for the Nuclear Safety and Radiation Protection Act; Cap. 585.

"National Radioactivity Monitoring Programme" means the system by which the environment is monitored for ionising radiation and the presence of radioactivity in environmental media, in accordance with regulation 95, in order to assess the levels of radiation and radioactivity in the environment to which the Maltese population is exposed;.

"natural radiation source" means a source of ionising radiation of natural, terrestrial or cosmic origin;

"non-medical imaging exposure" means any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;

"normal exposure" means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

"notification" means the requirement of submitting a document to the Secretariat to notify the intention to carry out a practice within the scope of these regulations;

"occupational exposure" means exposure of workers, apprentices and students, incurred in the course of their work;

"occupational health service" means a health professional or body competent to perform medical surveillance of exposed workers and whose capacity to act in that respect is recognised by the Commission;

"orphan source" means a radioactive source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost,

misplaced, stolen or otherwise transferred without proper authorisation;

"outside worker" means any exposed worker who is not employed by the undertaking responsible for the supervised and controlled areas, but performs activities in those areas, including, apprentices and students;

"planned exposure situation" means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures;

"potential exposure" means exposure that is not expected with certainty but may result from an event or sequence of events of a probabilistic nature, including equipment failures and operating errors;

"practical aspects of medical radiological procedures" means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing;

"practice" means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;

"practitioner" means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility and is approved by an undertaking in accordance with regulation 67;

"processing" means chemical or physical operations on radioactive material including the mining, conversion, enrichment of fissile or fertile nuclear material and the reprocessing of spent fuel;

"protective measures" means measures, other than remedial measures, for the purpose of avoiding or reducing doses that might otherwise be received in an emergency exposure situation or an existing exposure situation;

"public exposure" means exposure of individuals, excluding any occupational or medical exposure;

"quality assurance" means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance;

"quality control" means the set of operations (programming,

coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

"radiation generator" means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles;

"radiation protection" means protection of people from the harmful effects of exposure to ionising radiation, and the means for achieving of this protection;

"radiation protection expert" means an individual having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the Commission;

"radiation protection officer" means a individual designated by an undertaking, who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements given in an undertaking's radiation protection programme;

"radiation protection programme" means the systemic arrangements that are aimed at providing adequate consideration of radiation protection;

"radiation source" means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;

"radioactive material" means material incorporating radioactive substances;

"radioactive source" means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;

"radioactive substance" means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

"radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or material that the Commission requires to be regulated as radioactive waste;

"radiodiagnostic" means pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology;

"radiotherapeutic" means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;

"radon" means the radionuclide Rn-222 and its progeny, as appropriate;

"exposure to radon" means exposure to radon progeny;

"reference level" means in an emergency exposure situation or in an existing exposure situation, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded;

"referrer" means a medical doctor, dentist or other health professional who is authorised, in accordance with the undertakings procedures, to refer individuals for medical radiological procedures to a practitioner;

"registration" means permission granted in a document by the Secretariat, through a simplified procedure, to carry out a practice in accordance with conditions laid by the Commission for this type or class of practice;

"regulatory control" means any form of control or regulation applied to human activities for the enforcement of radiation protection requirements;

"remedial measures" means the removal of a radiation source or the reduction of its magnitude (in terms of activity or amount) or the interruption of exposure pathways or the reduction of their impact for the purposes of avoiding or reducing doses that might otherwise be received in an existing exposure situation;

"representative person" means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;

"safety assessment" means an assessment of all aspects of a practice that are relevant to radiation protection; for an authorised facility, this includes siting, design and operation of the facility in accordance with regulation 101;

"safety culture" means the assembly of characteristics and attitudes in organizations and individuals, which establishes that as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Safety culture includes:

(a) individual and collective commitment to safety on the part of the leadership, the management and personnel at all levels;

(b) accountability of organizations and of individuals at all levels for safety;

(c) measures to encourage a questioning and learning attitude and to discourage complacency with regard to safety;

"Secretariat" means the Secretariat of the Commission as established by article 12 of the Act;

"security" means the prevention and detection of, and response to, theft, sabotage, unauthorised access, illegal transfer or other malicious acts involving nuclear or other radioactive material, or their associated facilities;

"security culture" means characteristics and attitudes in organisations and of individuals which establish that security issues receive the attention warranted by their significance;

"sealed source" means a radioactive source in which the radioactive material is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions of use, any dispersion of radioactive substances;

"sievert" (Sv) is the special name of the unit of equivalent or effective dose. One sievert is equivalent to one joule per kilogram: 1 Sv =1 J kg^{-1} ;

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

"storage" means the holding of radioactive material, including spent fuel, a radioactive source or radioactive waste, in a facility with the intention of retrieval;

"supervised area" means an area subject to supervision for the purpose of protection against ionising radiation;

"source container" means an assembly of components intended to guarantee the containment of a sealed source, where it is not an integral part of the source but is meant for shielding the source during its transport and handling;

"standard values and relationships" means values and relationships recommended in chapters 4 and 5 of ICRP Publication 116 for the estimation of doses from external exposure and chapter 1 of ICRP Publication 119 for the estimation of doses from internal exposure, including updates approved by the Commission. The Commission may approve the use of specific methods in specified cases relating to the physico-chemical properties of the radionuclide or other features of the exposure situation or of the exposed individual;

"thoron" means the radionuclide Rn-220 and its progeny, as appropriate;

"technical service provider" means service providers in safety, providing either consultancy and maintenance services or calibration and testing services;

"undertaking" means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);

"unintended exposure" means medical exposure that is significantly different from the medical exposure intended for a given purpose.

Part III

SYSTEM OF RADIATION PROTECTION

General principles.

5. (1) The regulatory control regime is based on the principles of justification, optimisation and dose limitation as follows:

(a) Justification: Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.

(b) Optimisation: Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in regulation 66. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.

(c) Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

(2) The regulatory control regime shall make use of the graded approach.

(3) The prime responsibility for the safety and security of

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 affect safety and security.

Optimisation - use of dose constraints. *Substituted by: L.N. 184 of 2020.*

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;

(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.

Optimisation - use of Reference levels in existing and emergency situations. *Amended by: L.N. 184 of 2020.*

7. (1) Without prejudice to reference levels set for equivalent doses, that may be specified by the Commission, the reference levels for any persons expressed in effective doses shall be: 1mSv per year for existing exposure situations and 20mSv (acute or annual) for emergency exposure situations.

Provided that optimization of protection shall give priority to exposures above these reference levels and shall continue to be implemented below the reference level.

Provided that in specific situations the Commission may lower the reference levels taking into account optimisation and shall give due consideration to:

(a) a reference level below 20mSv may be set in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost;

(b) a reference level below 1mSv per year may be set, where appropriate, in an existing exposure situation for

specific source-related exposures or pathways of exposure

(2) For the transition from an emergency exposure situation to an existing exposure situation, appropriate reference levels shall be set, in particular upon the termination of long-term countermeasures.

(3) The reference levels set shall take account of the features of prevailing situations as well as societal criteria, which may include the following:

(a) for exposures below or equal to 1mSv per year, general information on the level of exposure, without specific consideration of individual exposures;

(b) in the range up to or equal to 20mSv per year, specific information to enable individuals to manage their own exposure, if possible

(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.

(4) For existing exposure situations involving exposure to radon, the reference levels shall be set in terms of radon activity concentration in air of 300 Bqm^{-3} for members of the public and workers.

Dose limitation - age limit for exposed workers. *Substituted by: L.N. 184 of 2020.*

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.

Dose limits for occupational exposure.

9. (1) The dose limits for occupational exposure apply to the sum of annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification in accordance with regulation 64(3), and other occupational exposure from existing exposure situations in accordance with regulation 124(3). For emergency occupational exposure regulation 63 shall apply.

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

(3) In addition to the limits on effective dose laid down in sub-regulation (2), the following limits on equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the

eye shall be 20mSv in a single year or 100mSv in any five consecutive years subject to a maximum dose of 50mSv in a single year;

(b) the limit on the equivalent dose for the skin shall be 500mSv in a year, this limit shall apply to the dose averaged over any area of 1 cm^2, regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 500mSv in a year.

Dose limitation for pregnancy and breastfeeding. S.L. 424.11 *Amended by: L.N. 184 of 2020.*

10. (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.

(2) As soon as workers inform the undertaking, or in case of outside workers, the employer of the outside worker, that they are breastfeeding an infant, they shall not be employed in work involving a significant risk of intake of radionuclides or of bodily contamination.

Dose limitation for apprentices and students.

11. (1) The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources, shall be the same as the dose limits for occupational exposure laid down in regulation 9.

(2) The limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources, shall be 6mSv in a year.

(3) In addition to the limits on effective dose laid down in sub-regulation (2), the following limits on equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the eye shall be 15mSv in a year;

(b) the limit on the equivalent dose for the skin shall be 150mSv in a year, this limit shall apply to the dose averaged over any area of 1cm^2, regardless of the area exposed;

(c) the limit on the equivalent dose for the extremities shall be 150mSv in a year

(4) The dose limits for apprentices and students who are not subject to the provisions of sub-regulations 1, 2 and 3 shall be the same as the dose limits for members of the public as specified in regulation 12

Dose limitation for public exposure.

12. (1) The effective dose limit for the public, applicable to any one authorised practise, shall be 0.25mSv per year.

(2) The limit of the sum effective dose for a member of the public resulting from all authorised practices is 1mSv in a year.

(3) In addition to the dose limit referred to in the sub-regulation (1), the following limits on the equivalent dose shall apply:

(a) the limit on the equivalent dose for the lens of the eye shall be 15mSv in a year;

(b) the limit on the equivalent dose for the skin shall be 50mSv in a year, this limit shall apply to the dose averaged over any area of 1 cm^2, regardless of the area exposed.

Estimation of the effective and equivalent dose.

13. For the estimation of effective and equivalent doses, the appropriate standard values and relationships shall be used. For external radiation, the operational quantities defined in section 2.3 of ICRP Publication 116 shall be used.

PART IV

RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

General training in radiation protection.

14. (1) The undertaking or, in case of outside workers, the employer of the outside worker shall ensure that individuals whose tasks require specific competences in radiation protection shall:

(a) have received appropriate radiation protection training before commencing work;

(b) that the radiation protection training is repeated, at intervals to be determined by the Commission but shall not exceed a period of 5 years; and

(c) keep records of training performed, including the training certificates.

(2) The Commission shall set a date by which all training shall be done in accordance to approved syllabi, as appropriate to field of practice, and delivered by approved organisations or individuals.

The Commission shall:

(a) approve syllabi for radiation protection training;

(b) approve organisations or individuals to provide

training; and

(c) accept as appropriate equivalent alternative radiation safety training where the individual has carried out prior training outside of Malta.

(3) Approved training organization or individual shall issue certificates of evidence that the Commission approved training has been performed.

Courses in medical and dental schools. *Added by: L.N. 184 of 2020.*

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. *Added by: L.N. 184 of 2020.*

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.

Work specific training of exposed workers and information provided to them.

15. (1) Undertakings are required to inform exposed workers on:

(a) the radiation health risks involved in their work;

(b) the general radiation protection procedures and precautions to be taken;

(c) the radiation protection procedures and precautions connected with the operational and working conditions of both the practice in general and each type of workstation or work to which they may be assigned;

(d) the relevant parts of the emergency response plans and procedures;

(e) the importance of complying with the technical, medical and administrative requirements.

In the case of outside workers, the employer of the outside worker shall ensure that the information required in paragraphs (a), (b), and (e) is provided.

(2) The undertaking or, in case of outside workers, the employer of the outside worker, is to inform exposed workers on the importance of making an early declaration of pregnancy in view of the risks of exposure for the unborn child.

(3) The undertaking or, in case of outside workers, the employer of the outside worker, to inform exposed workers on the importance of announcing the intention to breast-feed an infant in view of the risks of exposure for a breast-fed infant after intake of radionuclides or bodily contamination.

(4) The undertaking or, in case of outside workers, the

employer of the outside worker, provides appropriate radiation protection training and information programmes for exposed workers.

(5) In addition to the information and training in the field of radiation protection as specified in sub-regulations 1, 2, 3 and 4, the undertaking responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe and secure management and control of high-activity sealed sources with a view to preparing the relevant workers adequately for any events affecting the radiation protection. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

Information and training of workers potentially exposed to orphan sources.

16. (1) The Secretariat shall keep the customs authorities and metal recycling installations informed of the possibility that they may be confronted with a source.

(2) The Commission shall promote that workers in the customs authorities and in metal recycling installations are:

(a) advised and trained in the visual detection of sources and their containers;

(b) informed of basic facts about ionising radiation and its effects;

(c) informed of and trained in the actions to be taken on site in the event of the detection or suspected detection of a source.

Prior information and training for emergency. *Amended by: L.N. 184 of 2020.*

17. (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.

(2) In the event that an emergency occurs, the information referred to in the regulation 17(1a) shall be supplemented by Secretariat to emergency workers and any other persons involved, having regard to the specific circumstance.

Approval, Education, information and training in the field of medical exposure.

18. (1) Undertakings shall entitle individuals to act as referrers, practitioners and individuals involved in the practical aspects of medical radiological exposures by approving them and shall establish a procedure within its radiation protection programme for persons to be approved pursuant to the requirements of regulation 19.

(2) Referrers, practitioners and the individuals involved in the practical aspects of medical radiological procedures shall have the qualification and experience stated in the Seventeenth Schedule

Lists of individuals.

19. (1) Undertakings shall maintain lists of individuals that have been approved. These lists shall specify any limitations of the approval of individuals.

(2) Undertakings shall maintain the following records for each of its employees involved in medical exposures:

(a) name of individual;

(b) approval area, including: practitioner; person performing the practical aspects of medical equipment for medical purposes; person performing the practical aspects for other purposes;

(c) qualification certificates to demonstrate training (both academic and practical);

(d) examination results if applicable (including vision examinations pursuant to regulation 10 of the Minimum Health and Safety Requirements for Work with Display Screen Equipment Regulations) and their expiry;

S.L. 424.14.

(e) documentation of any continuing professional development;

(f) contract or signed statement of employment of the individual to act in the approved capacity.

(3) An undertaking may approve an individual to work in the same capacity on the basis that the individual has been approved by another undertaking provided that:

(a) the individual has proof of prior approval; and

(b) the individual was working in the same capacity in the last six months; and

(4) The approval of an undertaking shall be deemed revoked when:

(a) employment is terminated; or

(b) preliminary investigations for accidents indicate

gross individual negligence; or

(c) not carrying out approved work for six consecutive months.

Training programmes.

20. Individuals undergoing relevant training programmes may participate in practical aspects for the procedures mentioned in regulation 69 provided that they are constantly under direct supervision of a practitioner.

Education and training.

21. The undertaking shall facilitate the continuing education and training of its employees.

Resources. *Added by: L.N. 184 of 2020.*

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.

Clinical use of new techniques.

22. In the case of the clinical use of new techniques the undertaking shall provide training on these techniques and the relevant radiation protection requirements.

Part V

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

(SECTION 1)

Justification and prohibition of practices

Justification.

23. (1) It is prohibited to perform a class or type of practice that is not justified.

A list of classes and types of practice resulting in exposure to ionising radiation that are deemed justified at the time of this regulation being published is given in the Fourth Schedule.

(2) The Commission shall update and keep available a list of classes and types of practice resulting in exposure to ionising radiation that are deemed justified.

New class or types of practice.

24. The Commission shall not allow a new class or types of practice resulting in exposure to ionising radiation unless it deems it to be justified. If justified it shall be added to the list referred to in the regulation 23.

Review of existing classes or types of practices.

25. The Commission shall consider a review of existing classes or types of practices held on the list referred to in regulation 23 with regard to their justification whenever there is new and important evidence about their efficacy or potential consequences or new and important information about other techniques and technologies, if no longer justified they shall be removed from the list.

Medical exposure.

26. Practices involving medical exposure shall be a justified

practices pursuant to regulation 23 and each individual medical exposure shall be justified as specified in regulation 65.

Practices involving consumer products.

27. (1) Undertakings intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, to provide the Commission with all relevant information, including that listed in Section A of the Third Schedule, so as to allow the implementation of the justification requirement in regulation 25.

(2) The Commission shall assess this information and decide if the intended use of the consumer product is justified based on Section B of the Third Schedule.

(3) Without prejudice to sub-regulation (1), The Commission which has received information according to that sub-regulation, informs the point of contact for the competent authorities of other Member States of this receipt and, upon request, of its decision and the basis for that decision.

(4) It is prohibited to sale or the making available to the public of consumer products if their intended use is not justified or their use would not fulfil the criteria for exemption from notification under regulation 35.

Prohibited practices.

28. (1) It is prohibited to deliberately add radioactive substances in the production of foodstuffs, animal feeding stuffs, and cosmetics, and it is prohibited to import or export of such products.

S.L. 449.26.

(2) Without prejudice to the Irradiation of Food Regulations, practices involving the activation of material resulting in an increase in activity in a consumer product, which at the time of placing on the market cannot be disregarded from a radiation protection point of view, shall be deemed not to be justified. However, the Commission may evaluate specific types of practices within this class with regard to their justification.

(3) The deliberate addition of radioactive substances in the manufacture of toys and personal ornaments is prohibited and so is the import or export of such products.

(4) Practices involving the activation of materials used in toys and personal ornaments, resulting, at the time of the placing on the market of the products or of their manufacture, in an increase in activity, which cannot be disregarded from a radiation protection point of view is prohibited, and so is the import or export of such products or materials.

Deliberate exposures of humans for non-medical purposes.

29. (1) With regard to practices and applications involving non-medical imaging exposure the Commission shall:

(a) identify in the list referred to under regulation 23, practices and applications involving non-medical imaging

exposure which are deemed to be justified;

(b) review the general and particular justification of practices involving non-medical imaging exposures;

(c) regularly review the circumstances warranting non-medical imaging exposures, without individual justification of each exposure.

(2) Each particular application of an accepted type of practice, as stipulated by regulation 23, shall be justified by the undertaking and shall be subject to licensing by the Secretariat.

(3) With regard to practices and applications involving non-medical imaging exposure undertakings shall give special attention to justification in advance of all individual non-medical imaging exposure procedures using medical radiological equipment, taking into account the specific objectives of the procedure and the characteristics of the individual involved.

Justified practices.

30. Justified practices involving non-medical imaging exposure using medical radiological equipment may be exempted by the Commission from the requirement for dose constraints according to regulation 6(b) and from the dose limits set out in regulation 12.

Practices involving non-medical imaging exposure.

31. (1) For practices involving non-medical imaging exposure that are justified:

(a) the practice is subject to licensing which may impose specific requirements;

(b) for procedures using medical radiological equipment:

(i) relevant requirements identified for medical exposure as set out in Part VII are applied, including those for equipment, optimisation, responsibilities, training and special protection during pregnancy and the appropriate involvement of the medical physics expert;

(ii) where appropriate, specific protocols, consistent with the objective of the exposure and required image quality, are put in place;

(iii) where practicable, specific diagnostic reference levels are put in place;

(2) For procedures not using medical radiological equipment, shall have dose constraints that shall be established by the Commission and its value shall not exceed an effective dose of 0.25mSv per year for the individual exposed and ;

(3) Information is provided to and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities may proceed without consent of the individual according to Maltese legislation.

(SECTION 2)

Regulatory Control

Graded approach to regulatory control. *Substituted by: L.N. 184 of 2020.*

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.

Registers. *Added by: L.N. 184 of 2020.*

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.

Identification of practices involving naturally-occurring radioactive material.

33. The Commission shall identify classes or types of practice involving naturally–occurring radioactive material and leading to exposure of workers or members of the public which cannot be disregarded from a radiation protection point of view. Such identification shall be carried out by appropriate means taking into account industrial sectors listed in the Fifth Schedule.

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

(2) Undertakings shall immediately notify the Secretariat if

there is any change in the information supplied in connection with the above sub-regulation.

(3) Practices may be exempted from notification, as specified in regulation 35.

(4) Notification is required for workplaces specified in regulation 64(3) and for existing exposure situations that are managed as a planned exposure situation, as specified in regulation 124(3).

(5) Notwithstanding the exemption criteria laid down in regulation 35, in situations identified by the Commission where there is concern that a practice identified in accordance with regulation 33 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the Commission may require that the practice be subject to notification.

(6) Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with regulation 39 shall not be managed as a planned exposure situation and, hence, are not required to be notified.

Exemption from notification.

35. (1) The following justified practices do not need to be notified:

(a) radioactive materials where the quantities of the activity involved do not exceed in total the exemption values set out in Table B, Activity Column (Bq), of the Sixth Schedule, or higher values that, for specific applications, are approved by the Commission and satisfy the general exemption and clearance criteria set out in the Sixth Schedule ; or

(b) without prejudice to regulation 34(6) radioactive materials where the activity concentrations do not exceed the exemption values set out in Table A, Activity Concentration Column (kBq kg^{-1}), of the Sixth Schedule, or higher values that, for specific applications, are approved by the Commission and satisfy the general exemption and clearance criteria set out in the Sixth Schedule; or

(c) apparatus containing a sealed source, provided that:

(i) the apparatus is of a type approved by the Commission;

(ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding 1 μSv h^{-1} at a distance of 10cm from any accessible surface; and

(iii) conditions for recycling or disposal have

been specified by the Commission; or

(d) any electrical apparatus provided that:

(i) it is a cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kilo volt (kV), or it is of a type approved by the Commission; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding 1 μSv h^{-1} at a distance of 10cm m from any accessible surface.

(2) The Commission may exempt specific types of practices from the notification requirement subject to compliance with the general exemption criteria established in paragraph 3 of the Sixth Schedule, on the basis of an assessment showing that exemption is the best option.

Registration versus licensing.

36. (1) Registration or licensing is required for the following practices:

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

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

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

(3) The regulatory decision to submit types of practices to either registration or licensing shall use a graded approach and shall consider regulatory experience.

Licensing.

37. Licensing is required for the following practices:

(a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the operation and decommissioning of any nuclear facility;

(c) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products;

(d) any practice involving a high-activity sealed

source;

(e) the operation, decommissioning and closure of any facility for the long term storage or disposal of radioactive waste, including facilities managing radioactive waste for this purpose; the operation, decommissioning and closure of any facility for the long term storage or disposal of radioactive waste, including facilities managing radioactive waste for this purpose;

(f) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

Authorisation.

38. (1) In order to apply for a registration or license, applicants are to provide the Secretariat such information as shall be stipulated by the Secretariat.

(2) The information that the Secretariat will require to be supplied by applicants to apply for a license will include items in the indicative list in the Eighth Schedule.

(3) A licence shall include, as appropriate, specific conditions and reference to requirements in these regulations so as to ensure that the elements of the licence are legally enforceable, and impose appropriate restrictions on the operational limits and conditions of operation.

(4) Where applicable, the licence shall include conditions on the discharge of radioactive effluent, in connection with the requirements of regulation 87 for the authorisation of the release of radioactive effluent into the environment.

(5) Licensees shall notify the Secretariat at least one month prior to the expiry of their License to inform the Secretariat if they will be seeking a renewal of their license.

Release from regulatory control.

39. (1) Disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation.

(2) Materials for disposal, recycling or reuse may be released from regulatory control provided that the activity concentrations:

(a) for solid material do not exceed the clearance levels (kBq kg^{-1}) set out in Table A of the Sixth Schedule; or

(b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels shall be established by the Commission, following the general exemption and clearance criteria set out in paragraph 3 of Sixth Schedule, and taking into account technical

guidance provided by the European Union.

(3) The clearance of materials containing naturally-occurring radionuclides, where these result from authorised practices in which natural radionuclides are processed for their radioactive, fissile or fertile properties, the clearance levels comply with the dose criteria for clearance of materials out in paragraph 3 of Sixth Schedule ,

(4) It shall not be permitted to deliberately dilute radioactive materials for the purpose of them being released from regulatory control. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition. The Commission may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.

PART VI

OCCUPATIONAL EXPOSURES

Responsibilities.

40. (1) Undertakings are responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

(2) In the case of outside workers, the responsibilities of the undertaking and the employer of outside workers are stipulated in regulation 61.

(3) Without prejudice to sub-regulations 1 and 2, there shall be a clear allocation of responsibilities, specified within radiation protection programme of the undertaking , for the protection of workers in any exposure situation, to an undertaking, an employer of the outside worker or any other organisation, in particular for the protection of:

(a) emergency workers;

(b) workers involved in the remediation of contaminated land, buildings and other constructions;

(c) workers who are exposed to radon at work, in the situation specified in regulation 64(3),

This shall also apply to the protection of self-employed individuals and individuals who work on a voluntary basis.

(4) Employers of outside workers shall ensure that they have access to information on the possible exposure of their employees under the responsibility of another employer or undertaking.

Operational protection of exposed workers.

41. (1) Operational protection of exposed workers shall be based on:

(a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers as part of the safety assessment required by regulation 101;

(b) optimisation of radiation protection in all working conditions;

(c) classification of exposed workers as either category A worker or category B worker;

(d) control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring;

(e) medical surveillance;

(f) education and training.

Operational protection of apprentices and students.

42. (1) Exposure conditions and operational protection of apprentices and students aged 18 years or over referred to regulation 11(1) is equivalent to that of exposed workers of category A or B as appropriate.

(2) Exposure conditions and operational protection of apprentices and students aged between 16 and 18 years referred to in regulation 11(2) is equivalent to that of exposed workers of category B.

Consultations with a radiation protection expert.

43. Undertakings shall seek advice from a radiation protection expert within the radiation protection expert's areas of competence (as outlined in regulation 105), on the issues below that are relevant to the practice:

(a) the examination and testing of protective devices and measuring instruments;

(b) prior critical review of plans for installations from the point of view of radiation protection;

(c) the acceptance into service of new or modified radiation sources from the point of view of radiation protection;

(d) regular checking of the effectiveness of protective devices and techniques;

(e) regular calibration of measuring instruments and regular checking that they are serviceable and correctly used;

(f) radiation protection programme of the undertaking.

Arrangements in workplaces.

44. (1) Undertakings shall give careful consideration and implement radiation protection arrangements as regards all workplaces where workers are liable to receive an exposure greater than an effective dose of 1mSv per year or an equivalent dose of 15mSv per year for the lens of the eye or 50mSv per year for the skin and extremities.

Such arrangements shall use the graded approach.

(2) For workplaces specified in regulation 64(3) and where the exposure of workers is liable to exceed an effective dose of 6mSv per year or a corresponding time-integrated radon exposure value of 300Bq/m^3, these shall be managed as a planned exposure situation and the Commission shall determine which requirements set out in this Part VI are appropriate. For workplaces specified in regulation 64(3), and where the effective dose to workers is less than or equal to 6mSv per year or the exposure less than the corresponding time-integrated radon exposure value for the workers, the Commission shall require that exposures are kept under review.

(3) For an undertaking operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6mSv per year, the relevant requirements set out in this Part VI shall apply, allowing for the specific features of this exposure situation. In the case that an effective dose to the crew is liable to be above 1mSv per year, the undertaking is take appropriate measures, in particular:

(a) to assess the exposure of the crew concerned;

(b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew;

(c) to inform the workers concerned of the health risks their work involves and their individual dose;

(d) to apply regulation 10(1) to pregnant air crew.

Classification of workplaces.

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

(2) Undertakings shall designate as a controlled area any area under his control which:

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

(b) any person working in the area is likely to

receive an effective dose greater than 6mSv a year or an equivalent dose greater than three-tenths of any relevant dose limit referred to in these regulations.

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

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

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

(4) Undertakings shall keep under review the working conditions in controlled and supervised areas.

Controlled areas.

46. (1) The minimum requirements for a controlled area are the following:

(a) The controlled area shall be delineated and access to it shall be restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking. Wherever there is a significant risk of the spread of radioactive contamination, specific arrangements shall be made, including for the access and exit of individuals and goods and for monitoring contamination within the controlled area and, where appropriate, in the adjacent area.

(b) Taking into account the nature and extent of radiological risks in the controlled area, radiological surveillance of the workplace shall be organised in accordance with the provisions of regulation 48.

(c) Signs indicating that the area is Controlled, the nature of the sources and their inherent risks shall be displayed.

(d) Working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

(e) The worker shall receive specific training in connection with the characteristics of the workplace and the activities.

(f) The worker shall be provided with the appropriate personal protective equipment.

(2) The undertaking is responsible for implementation of

these duties taking into account the advice provided by the radiation protection expert.

Supervised areas.

47. (1) The requirements for a supervised area are the following:

(a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the workplace shall be organised in accordance with the provisions of regulation 48;

(b) signs indicating that the area is Supervised, the nature of the sources and their inherent risks shall be displayed;

(c) if appropriate, working instructions appropriate to the radiological risk associated with the sources and the operations involved shall be laid down.

(2) The undertaking is responsible for implementation of these duties taking into account the advice provided by the radiation protection expert.

Radiological surveillance of the workplace.
Amended by: L.N. 184 of 2020.

48. (1) Undertakings shall ensure that the radiological surveillance of the workplace referred to in paragraph (b) of regulation 46(1) and paragraph (a) of regulation 47(1) comprises, where appropriate:

(a) the measurement of external dose rates, indicating the nature and quality of the radiation in question;

(b) the measurement of the activity concentration in air and the surface density of contaminating radionuclides, indicating their nature and their physical and chemical states.

(2) Results of these measurements shall be recorded and shall be used, if necessary, for estimating individual doses, as provided for regulation 50.

(3) The results of radiological surveillance of the workplace shall be kept for a minimum of two years.

(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.

Categorisation of exposed workers.

49. (1) For the purposes of monitoring and surveillance, every undertaking shall designate exposed workers into one of two categories:

(a) category A: those exposed workers who are liable to receive an effective dose greater than 6mSv per year or an equivalent dose greater than 15mSv per year for the lens of the eye or greater than 150mSv per year for skin and

extremities;

(b) category B: those exposed workers who are not classified as category A workers.

(2) The undertaking or, in the case of outside workers, the employer of the outside worker, shall decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and to regularly review this categorisation on the basis of working conditions and medical surveillance. The distinction shall also take into account potential exposures.

Individual monitoring.

50. (1) Undertakings shall ensure that category A workers are systematically monitored based on individual measurements performed by a dosimetry service. In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up.

(2) Undertakings shall ensure that monitoring for category B workers is at least sufficient to demonstrate that such workers are correctly classified in category B. The Secretariat may require the undertaking to perform individual monitoring and if necessary individual measurements, by a dosimetry service, for category B workers.

(3) In cases where individual measurements are not possible or inadequate, the individual monitoring shall be based on an estimate arrived at from individual measurements made on other exposed workers, from the results of the surveillance of the workplace provided for in regulation 48 or on the basis of calculation methods approved by the Secretariat.

Dose assessment in the case of accidental exposure.

51. (1) In the case of accidental exposure, the undertaking is required to assess the relevant doses and their distribution in the body.

(2) In the case of accidental exposure, the undertaking is required to obtain the results of dose assessments as soon as practically possible.

Recording and reporting of results.

52. (1) Undertakings and the employer of any outside workers shall record the data specified in paragraph 1 of the Ninth Schedule for the individual monitoring that is made for category A workers and any individual monitoring that is performed on category B workers.

(2) For the purposes of sub-regulation (1), the following information on exposed workers shall be retained:

(a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to regulations 50, 51, 61, 62, 63 and, if required by the Secretariat pursuant to

regulations 44(2), 64(3);

(b) in the case of exposures as referred to in regulations 51, 62, 63, the reports relating to the circumstances and the action taken;

(c) the results of workplace monitoring used to assess individual doses where necessary.

(3) The information referred to in sub-regulation (1) shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

(4) Exposures as referred to in regulations 51, 62, 63, and, if decided by the Secretariat pursuant to regulations 44(2), 64(3) shall be recorded separately in the dose record referred to in sub-regulation (1).

(5) The dose record referred to in sub-regulation (1) shall be submitted to the Secretariat by the thirtieth day of April for the following year in the format specified by the Secretariat and shall consist of the data in Section 2 of the Ninth Schedule.

(6) The Secretariat may seek to verify any of the data supplied.

Access to the results of individual monitoring.

53. (1) The results of the individual monitoring set out in regulations 50, 51, 62, 63 shall pursuant to regulations 44(2), 64(3) be:

(a) submitted to the Secretariat, to the undertaking, and to the employer of outside workers;

(b) made available to the worker concerned in accordance with sub-regulation (2);

(c) submitted to an occupational health service in order for it to interpret the implications of the results for human health, as provided for in regulation 55(2).

(2) The undertaking, or in case of outside workers, the employer of the outside worker, to grant workers, at their request, access to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of surveillance of the workplace.

(3) In the case of an accidental exposure, the undertaking shall communicate the results of individual monitoring and dose assessments to the individual and the Secretariat without delay.

(4) It is the responsibility of the undertaking and the employer of the outside worker that arrangements are in place for the appropriate exchange, among the undertaking, in the case of an outside worker, the employer, the Secretariat, occupational health services, radiation protection experts, or dosimetry services of all relevant information on the doses previously received by a worker in order to perform the medical examination prior to employment or classification as a category A worker pursuant to regulation 55 and to control the further exposure of workers.

Data on outside workers to be supplied.

54. (1) Before the start of any activity, the employer of the outside worker shall supply the data given in paragraph 3 of the Ninth Schedule to the undertaking data on the employment of the outside worker.

(2) The following data shall be recorded or have been recorded by the undertaking in the data system for individual radiological monitoring after the end of any activity for the outside worker:

(a) the period covered by the activity;

(b) an estimate of any effective dose received by the outside worker (for the period covered by the activity);

(c) in the event of non-uniform exposure, an estimate of the equivalent doses in the different parts of the body;

(d) in the event of an intake of radionuclides, an estimate of the intake or the committed effective dose.

Medical surveillance of exposed workers.

55. (1) Medical surveillance of exposed workers shall be based on the principles that govern occupational medicine generally.

(2) The medical surveillance of category A workers shall be undertaken by an occupational health service. This medical surveillance shall allow for the state of health of workers under surveillance to be ascertained as regards their fitness for the tasks assigned to them. To this end, the occupational health service shall have access to any relevant information they require, including the environmental conditions in the working premises.

(3) Medical surveillance shall include:

(a) a medical examination prior to employment or classification as a category A worker to determine the worker's fitness for a post as a category A worker for which the worker is being considered;

(b) periodic reviews of health at least once a year, in order to determine whether the category A workers remain fit to perform their duties. The nature of these reviews, which can be performed as many times as an occupational health service

considers necessary, shall depend on the type of work and on the individual worker's state of health.

(4) An occupational health service may indicate the need for medical surveillance to continue after cessation of work for as long as they consider it necessary to safeguard the health of the person concerned.

Medical classification.

56. Workers shall have one of the following medical classifications with respect to fitness for work as a category A worker:

(a) a fit;

(b) fit, subject to certain conditions;

(c) unfit.

Prohibition to employ or classify unfit workers.

57. No worker may be employed or classified for any period in a specific post as a category A worker if medical surveillance establishes that the worker is unfit for that specific post.

Medical records.

58. (1) Medical records shall be opened for each category A worker and kept up to date so long as the worker remains a worker in that category. Thereafter, it shall be retained until the individual has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation.

(2) The medical record shall include information regarding the nature of the employment, the results of the medical examinations prior to employment or classification as a category A worker, the periodic reviews of health and the record of doses required by regulation 52.

Special medical surveillance.

59. (1) In addition to the medical surveillance of exposed workers provided for in regulation 55, provision is made for any further action considered necessary by an occupational health service for the health protection of exposed individuals, such as further examinations, decontamination measures, urgent remedial treatment or other actions identified by the occupational health service.

(2) Special medical surveillance shall be performed in each case where any of the dose limits laid down in regulation 9 has been exceeded.

(3) Subsequent exposure conditions shall be subject to the agreement of the occupational health service.

Appeals.

60. Workers may appeal to the Commission against the findings and decisions made pursuant to regulations 56, 57 and 59.

Protection of outside workers.

61. (1) The system for individual radiological monitoring shall afford outside workers equivalent protection to that for exposed workers employed on a permanent basis by the undertaking.

(2) The undertaking is responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers that are directly related to the nature of their activities in the undertaking.

(3) In particular, as a minimum requirement, the undertaking shall:

(a) for category A workers entering controlled areas, check that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker;

(b) check whether the categorisation of the outside worker is appropriate in relation to the doses liable to be received within the undertaking;

(c) for entry into controlled areas, ensure that, in addition to the basic training in radiation protection the outside worker has received specific instructions and training in connection with the characteristics of the workplace and the conducted activities, in accordance with paragraphs (c) and (d) of regulation 15(1);

(d) for entry into supervised areas, ensure that the outside worker has received working instructions appropriate to the radiological risk associated with the sources and the operations involved, as required in paragraph (c) of regulation 47(1);

(e) ensure that the outside worker has been issued with the necessary personal protective equipment;

(f) ensure that the outside worker receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;

(g) ensure compliance with the system of protection as defined in Part III;

(h) for entry into controlled areas, ensure or take all appropriate steps to ensure that after every activity the radiological data from individual exposure monitoring of each category A outside worker within the meaning of the regulation 54(2), are recorded.

(4) Employers of outside workers ensure, either directly or through contractual agreements with the undertaking, that the radiation protection of their workers is in accordance with the relevant

provisions of these regulations, in particular by:

(a) ensuring compliance with the system of protection as defined in Part III;

(b) ensuring that the information and training in the field of radiation protection referred to in paragraphs (a), (b) and (e) of regulation 15(1), regulations 15(2), 15(3), 15(4) is provided;

(c) guaranteeing that their workers are subject to appropriate assessment of exposure and, for category A workers, medical surveillance, under the conditions laid down in regulations 48 and 50 to 59;

(d) ensuring that the radiological data from the individual exposure monitoring of each of their category A workers is kept up to date in the data system for individual radiological monitoring referred to in paragraph (a) of regulation 53.

Specially authorised exposures. *Amended by: L.N. 184 of 2020.*

62. (1) The Secretariat may decide that in exceptional circumstances evaluated case by case, excluding emergencies, where a specific operation so requires, authorise individual occupational exposures of identified workers exceeding the dose limits set out in regulation 9 provided that such exposures are limited in time, confined to certain working areas and within the maximum exposure levels defined for the particular case by the Secretariat. The following conditions shall be taken into account:

(a) only category A workers as defined in regulation 49 may be subject to such exposures;

(b) apprentices, students, pregnant workers, and, if there is a risk of intake or bodily contamination, breastfeeding workers, are excluded from such exposures;

(c) the undertaking justifies such exposures in advance and thoroughly discuss them with the workers, their representatives, an occupational health service and the radiation protection expert;

(d) information about the risks involved and the precautions to be taken during the operation are provided to the relevant workers in advance;

(e) the workers have consented;

(f) all doses relating to such exposures are separately recorded in the medical record referred to in regulation 58 and the individual record referred to in regulation 52.

(2) The exceeding of dose limits as a result of specially authorised exposures shall not necessarily constitute a reason for excluding workers from their usual occupation or relocating them, without their agreement.

(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.

Emergency occupational exposure. *Amended by: L.N. 184 of 2020.*

63. (1) Emergency occupational exposures shall remain, whenever possible, below the values of the dose limits laid down in regulation 9.

(2) For situations where the above condition is not feasible, the following conditions shall apply:

(a) reference levels for emergency occupational exposure shall be an effective dose of 50mSv;

(b) in exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, a reference level for an effective dose from external radiation of emergency workers shall be 500mSv.

(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.

(4) In the event of an emergency occupational exposure, radiological monitoring of emergency workers shall be performed. Individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.

(5) In the event of an emergency occupational exposure, medical surveillance of emergency workers shall be required, as defined in regulation 59, to be carried out as appropriate to the circumstances.

Radon in workplaces.

64. (1) The national reference level for the annual average activity concentration for indoor radon concentrations in air is 300 Bqm^{-3} for workplaces.

(2) Radon measurements shall be carried out:

(a) in workplaces within the areas identified by the Commission in accordance with regulation 127(3), that are located on the ground floor or basement level or any other subterranean work places; as well as

(b) in specific types of workplaces identified in the national action plan taking into account paragraph 3 of the Sixteenth Schedule.

(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, notification in accordance with regulations 34(4) and 44(2) shall apply.

Part VII

MEDICAL EXPOSURES

Justification. *Amended by: L.N. 184 of 2020.*

65. (1) Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

(2) Undertakings shall apply the justification principle defined in sub-regulation (1) is applied and in particular that:

(a) It is ensured that both the referrer and the practitioner shall make reference to referral guidelines.

(b) Undertakings inform and supply supporting justification documentation to the Commission in advance of that undertaking adopting any new types of practices involving medical exposure.

(c) All individual medical exposures are to be justified in advance by a practitioner taking into account the specific objectives of the exposure and the characteristics of the individual involved.

(d) Specific individual exposures can be justified, where appropriate, in special circumstances, to be evaluated by a practitioner on a case-by-case basis and documented for practices involving medical exposure that are not justified in general.

(e) The referrer and the practitioner, shall seek, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure. Repeat of medical exposure is not justified if the diagnostic information is already available.

(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.

(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.

(h) The exposure of carers and comforters shall show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carer / comforter and the detriment that the exposure might cause.

(i) Medical radiological procedure for the early detection of disease on an asymptomatic individual can only be performed if it is:

(i) part of a health screening programme, or

(ii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the Commission.

Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by paragraph (e) of regulation 68.

(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.

Optimisation.
Amended by: L.N. 184 of 2020.

66. (1) All doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are to be kept as low as reasonably achievable

consistent with obtaining the required medical information, taking into account economic and societal factors.

(2) For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

(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.

(4) For each medical or biomedical research project involving medical exposure:

(a) the individuals concerned participate voluntarily;

(b) these individuals are informed about the risks of exposure;

(c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

(d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

(5) Undertakings shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

(6) Undertakings shall ensure that:

(a) a dose constraints of not more than 1.5mSv per five years is applied exposure of carers and comforters, where appropriate;

(b) appropriate guidance is established for the exposure of carers and comforters.

(7) In the case of a patient undergoing treatment or

diagnosis with radionuclides, the undertaking, shall ensure that the patient or their representative is provided with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic.

Approval and responsibilities.

67. The undertaking shall entitle individuals to act in the different aspects of medical exposures by approving these individuals.

The undertaking is responsible to approve any individual whose work relates to medical exposure. In making such approvals the undertaking shall ensure that the individual meets the requirements of the Seventeenth Schedule.

Undertakings.

68. Undertakings shall ensure that:

(a) medical exposures shall take place under the clinical responsibility of a practitioner;

(b) in medical radiological practices, a medical physics expert shall be appropriately involved, the level of involvement being commensurate with the radiological risk posed and is given in the Table 1 of the Twentieth Schedule;

(c) practitioners, medical physics experts and those entitled to carry out practical aspects of medical radiological procedures shall be involved in the optimization process;

(d) referrers and practitioners shall liaise as required with each another in the justification process of individual medical exposures;

(e) wherever practicable and prior to the exposure taking place, the practitioner and the referrer, is to ensure that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters, in accordance with paragraph (b) of regulation 66(6).

Practical aspects of medical radiological procedures.

69. Practical aspects of medical radiological procedures may be delegated by the undertaking or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialization authorised by the Commission to act in this respect.

Procedures.

70. Undertaking's radiation protection programmes shall include that:

(a) written protocols for every type of standard medical radiological procedure are established for each equipment for relevant categories of patients;

(b) information relating to patient exposure forms part of the report of the medical radiological procedure;

(c) referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers;

(d) clinical audits are carried out in accordance to the national procedures established by the Commission;

(e) appropriate reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay;

(f) procedures are in place for:

(i) the correct identification of individuals to be exposed to ionising radiation;

(ii) making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;

(iii) approval of individuals to act as referrers, practitioners, and persons performing the practical aspects;

(iv) quality assurance;

(v) the assessment of patient dose and administered activity;

(vi) medical and biomedical research programmes including the use of dose constraints;

(vii) giving of information and written instructions as referred to in regulation 66(7);

(viii) recording of doses for each medical exposure including, where appropriate, factors relevant to patient dose;

(ix) ensuring that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced as far as reasonably achievable;

(x) responding and reporting of incidents and accidents;

(xi) record keeping;

(xii) arrangements for monitoring workers and the workplace;

(xiii) education and training programme on the nature of the hazards, protection and safety;

(xiv) methods for periodically reviewing and auditing the performance of the radiation protection programme;

(xv) any others as required to be able to demonstrate compliance with these regulations.

Training and recognition. *Amended by: L.N. 184 of 2020.*

71. (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.

(2) Undertakings shall ensure that practitioners and medical physics experts and the individuals referred to in regulation 69 meet the requirements of the above sub-regulation (1).

Equipment. *Substituted by: L.N. 184 of 2020.*

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..

Installation of the equipment.

73. Upon installation of the equipment the supplier/installer has to perform tests to ensure that all the safety features and warning devices of the equipment are functioning. During installation, the manufacturer's instructions for use must be followed. These tests shall be performed whenever new, second hand; refurbished and relocated equipment has been installed, as well as after major maintenance has been performed. These test results have to be kept by the undertaking.

Acceptance testing.

74. (1) Acceptance testing must be carried out in accordance with international standards. The standard to be used shall be accepted by the Commission.

(2) Acceptance tests need to be carried out on installation or relocation of equipment.

Testing for performance, equivalent to an acceptance test or parts thereof shall be carried out:

(a) after major adjustments of functional parameters, repairs or maintenance have been performed;

(b) after components or sub-assemblies have been added, modified, replaced or removed;

(c) after each time the undertaking has to remove the

equipment from clinical use due to a malfunction or maintenance that could affect the patient dose;

(d) if tests show that the equipment has or is producing doses other than the acceptable levels.

(3) Acceptance test results should be compared to and meet the manufacturer's tolerances. In the absence of such, as in the case of aged equipment then European Union criteria for acceptability may be used.

(4) After the acceptance testing is carried out, the test reports and any other relevant documentation has to be passed on the Secretariat. The Information to be supplied to the Secretariat with regard to acceptance tests that have been performed is given in the Eighteenth Schedule

(5) The records for such testing shall be kept for the lifetime of the equipment.

(6) In order to set up the optimal clinical operation of the equipment, certain commissioning tests may be required to be performed, such as setting up exposure protocols.

Constancy testing.

75. (1) Constancy testing must be carried out in accordance with international standards. The standard to be used shall be accepted by the Commission.

(2) Constancy tests are to be performed:

(a) immediately after an the initial acceptance test has indicated that the functional performance of the equipment is satisfactory;

(b) as often as the standard stipulates but shall not exceed two years;

(c) immediately after corrective maintenance that could effect the radiation output of the equipment or;

(d) when malfunction of equipment is suspected.

(3) Constancy tests records of shall be kept for three years from the last date of entry.

Recalibrated equipment. *Substituted by: L.N. 184 of 2020.*

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.

Acceptable levels.

77. (1) If tests show that the equipment has or is producing doses other than the acceptable levels, or a malfunction

has occurred that could affect patient dose, it shall be removed from clinical use and shall be reported to the Secretariat.

(2) Acceptable levels are deemed the tolerances specified in the manufacturer's specifications or the current European Union Criteria which ever is the most stringent.

Clearance for clinical use.

78. (1) Clearance for the clinical use of the equipment is required from the Secretariat for all instances specified in regulation 74(2).

(2) Clearance will only be issued after the Secretariat reviews the acceptance tests required by regulation 74(1).

Compliance.
Amended by: L.N. 184 of 2020.

79. (1) The undertaking shall ensure that:

(a) all new equipment has an EC Declaration of conformity;

(b) all new equipment has, where practicable, a device showing the quantity of the radiation produced by the equipment;

(c) an up to date inventory of radiological equipment for each radiological installation is available;

(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;

(e) when in use the equipment must be adequately supervised to ensure an adequate level of radiation protection;

(f) appropriate routine maintenance is performed (in line with manufactures recommendations);

(g) appropriate quality assurance programmes are in place, including a schedule for testing the equipment;

(h) appropriate quality assurance programmes for assessing patient dose or administered activity;

(i) suitable measures are taken to improve inadequate or defective features of the equipment;

(j) that there are suitable measures for putting equipment into clinical use and removal from clinical use;

(k) there is clear allocation of responsibilities for who can declare that the equipment is fit/unfit for clinical use;

(l) adopt specific criteria of acceptability for equipment in order to indicate when appropriate remedial action

is necessary, including, if appropriate, taking the equipment out of service;

(m) reasonably steps to prevent failure of radiation equipment where such failure could result in exposure of patients to ionising radiation greater than intended;

(n) on becoming aware of defects in equipment during use, the undertaking assesses in consultation with the supplier (or where relevant the service agent or original manufacturer) and the medical physics expert, if appropriate, whether any further action is necessary;

(o) shall have a contingency plan for responding to equipment failures or malfunction. Following equipment failure and subsequent repair, the undertaking should consider the likelihood and consequences of recurrence before returning the equipment to clinical use.

(2) If the equipment is going to be taken out of clinical use, with no intention of scrapping, then the undertaking shall remain responsible for that equipment and if the equipment is sold, leased or given to another approved undertaking, than the Secretariat shall be notified prior to this happening.

80. Specific requirements for certain equipment:

Specific requirements.

(a) the use of fluoroscopy equipment without a device to automatically control the dose rate, or without an image intensifier or equivalent device, is prohibited.

(b) equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

(c) any equipment used for interventional radiology has a device or a feature informing the practitioner and those carrying out practical aspects of the medical procedures of quantity of radiation produced by the equipment during the procedure. Equipment installed prior to 6 February 2018 may be exempted from this requirement.

(d) any equipment used for interventional radiology and computed tomography and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose.

(e) equipment used for interventional radiology and computed tomography has the capacity to transfer the information required under 3(d) to the record of the examination. Equipment installed prior to 6 February 2018

may be exempted from this requirement.

(f) without prejudice to paragraphs (c), (d) and (e), new medical radiodiagnostic equipment producing ionising radiation has a device, or an equivalent means, informing the practitioner of relevant parameters for assessing the patient dose. Where appropriate, the equipment shall have the capacity to transfer this information to the record of the examination.

Special practices.

81. (1) Appropriate medical radiological equipment, practical techniques and ancillary equipment shall be used in medical exposure:

(a) of children;

(b) as part of a health screening programme;

(c) involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy.

(2) Special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

(3) Practitioners and those individuals referred to in regulation 69 who perform the exposures referred to in sub-regulation (1) shall obtain appropriate training on these medical radiological practices as required by regulation 18.

Special protection during pregnancy and breastfeeding.

82. (1) The referrer and the practitioner, shall inquire, as whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.

(2) If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.

(3) In the case of a breastfeeding individual, in nuclear medicine, depending on the medical radiological procedure, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the individual and the child.

(4) Without prejudice to sub-regulations 1, 2 and 3, undertakings shall take measures to increase the awareness of individuals to whom this regulation applies, through measures such as public notices in appropriate places.

Accidental and unintended exposures.

83. Undertakings shall ensure that

(a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;

(b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;

(c) for all medical exposures that appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;

(d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;

(e) declares within two days to the Secretariat the occurrence of medical exposures much greater than intended and other significant events as defined in the Nineteenth schedule;

(f) the results of the investigation and the corrective measures to avoid such events are reported to the Secretariat within one week;

(g) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Estimates of population doses.

84. Undertakings shall ensure that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined, taking into consideration the age and gender of the exposed and that this information is made available to the Secretariat.

PART VIII

PUBLIC EXPOSURES

(SECTION 1)

PROTECTION OF MEMBERS OF THE PUBLIC AND LONG-TERM HEALTH PROTECTION IN NORMAL CIRCUMSTANCES

Operational protection of members of the public.

85. (1) Licensees shall ensure that the operational protection of members of the public in normal circumstances from their practice and shall include, for relevant facilities, the following:

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

(b) adequate protection being provided against any exposure or radioactive contamination liable to extend beyond the perimeter of the facility or radioactive contamination liable to extend to the ground beneath the facility;

(c) measures to control the access of members of the public to the facility.

(2) Practices subject to registration shall ensure the protection of members of the public in normal circumstances.

Estimation of doses to the members of the public.

86. (1) Undertakings shall estimate doses to members of the public (which excludes occupational and medical doses) from their practices.

(2) Undertakings shall provide the following information with regard to public doses:

(a) An estimate of public doses prior to the commencement of the practice.

(b) Initial measurements of the relevant parameters to confirm their estimate given, above once the practice is functioning.

(c) Results of routine re-assessments and measurements of the relevant parameters are performed.

(3) The Secretariat shall in particular:

(a) decide on a reasonable extent of surveys to be conducted and information to be taken into account in order to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;

(b) decide on a reasonable frequency of monitoring of the relevant parameters as determined in paragraph (a);

(c) ensure that the estimates of doses to the representative person include:

(i) assessment of the doses due to external radiation, indicating, where appropriate, the type of the radiation in question;

(ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where

necessary, their physical and chemical states, and determination of the activity concentrations of these radionuclides in food and drinking water or other relevant environmental media;

(iii) assessment of the doses that the representative person, as identified in paragraph (a), is liable to receive;

(d) require records relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person to be kept and be made available on request to all stakeholders.

Radioactive discharges.

87. (1) Pursuant to regulation 37(f), undertakings who wish to discharge radioactive effluents shall apply to the Secretariat for a discharge license.

(2) Undertakings shall provide to the Secretariat an estimate of doses to individuals from the proposed discharges using generic screening assessment based on internationally recognised scientific guidance as part of their application for a discharge license.

(3) The Secretariat shall examine and approve plans for the discharge of radioactive effluents and issue a discharge license.

(4) The Secretariat shall where appropriate establish authorised limits as part of the discharge license and conditions for discharging radioactive effluents which shall:

(a) take into account the results of the optimisation of radiation protection;

(b) reflect good practice in the operation of similar facilities.

(5) The Secretariat shall require the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately or where appropriate evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results annually to the Secretariat.

Tasks for the undertaking.

88. Undertaking shall carry out the following tasks:

(a) achieve and maintain an optimal level of protection of members of the public;

(b) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment;

(c) check the effectiveness and maintenance of equipment as referred to in paragraph (b) and ensure the annual recalibration of measuring instruments;

(d) seek advice from a radiation protection expert in the performance of the tasks referred to in paragraphs (a), (b) and (c).

(SECTION 2)

EMERGENCY EXPOSURE SITUATIONS

Emergency response. *Amended by: L.N. 184 of 2020.*

89. (1) The Commission shall develop and maintain the national radiological emergency plan referred to in Article 31 of the Act in consultation with the Civil Protection Department.

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

(3) The national radiological protection plan shall be tested at appropriate intervals.

Notification.

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.

Emergencies on or outside Maltese territory. *Substituted by: L.N. 184 of 2020.*

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.

Medical treatment.

92. If the situation so requires, ensure that provision is made to organise the medical treatment of those affected by the Ministry of Health with the Secretariat providing any required advice.

Information to the members of the public likely to be affected in the event of an emergency.

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.

Information to the members of the public actually affected in the event of an emergency.

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.

(SECTION 3)

EXISTING EXPOSURE SITUATION

Environmental monitoring programme.

95. (1) The Commission shall ensure that the National Radioactivity Monitoring Programme is maintained.

(a) In connection with the National Radioactivity Monitoring Programme:

(b) The Commission shall ensure that the appropriate government entities have an environmental monitoring programme for ionizing radiation and radioactivity, as part of the National Radioactivity Monitoring Programme, and in doing so take into consideration any recommendations from the European Commission. The minimum elements of the national monitoring programme are given in the Table 1 of the Twenty First Schedule.

(c) Entities performing the monitoring for the National Radioactivity Monitoring Programme shall enter into a formal arrangement with the Commission for the provision of the result data.

(d) The entity performing the monitoring and the Commission shall review the results.

(e) The Commission shall collate the results and send them to European Commission as required.

(f) The Commission shall Produce an annual report of the results which may be made public.

(2) The Secretariat shall require undertakings to perform environmental monitoring as appropriate in connection with their practices.

Contaminated areas.

96. (1) The Commission shall ensure that optimised protection strategies for managing contaminated areas shall include, where applicable, the following:

(a) objectives, including long-term goals pursued by the strategy and corresponding reference levels, in accordance with regulation 7;

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

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

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

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

(2) For areas with long-lasting residual contamination in which the Commission has advised the government to allow habitation and the resumption of social and economic activities, the government, following the advice of the Commission, shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:

(a) establishment of appropriate reference levels;

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

(c) if appropriate, remediation measures;

(d) if appropriate, delineated areas.

Indoor exposure to radon.

97. (1) The reference level for the annual average activity concentration in air shall is 300 Bq m^{-3}.

(2) Under the national action plan referred to in regulation 127, The Commission shall promote action to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourage, where appropriate by technical or other means, radon concentration-reducing measures in these dwellings.

(3) The Commission shall ensure that national information is made available on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing radon concentrations.

Gamma radiation from building materials.

98. (1) The reference level applying to indoor external exposure to gamma radiation emitted by building materials, in addition to outdoor external exposure, shall be 1mSv per year.

(2) For building materials which are identified by the Commission as being of concern from a radiation protection point of view, taking into account the indicative list of materials set out in the Twelve Schedule with regard to their emitted gamma radiation, it shall be ensured that, before such materials are placed on the market:

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

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

(3) For types of building materials identified in accordance

with sub-regulation (2) which are liable to give doses exceeding the reference level, The Commission shall decide on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials.

Part IX

RESPONSIBILITIES AND OTHER ELEMENTS OF REGULATORY CONTROL

(SECTION 1)

GENERAL RESPONSIBILITIES OF UNDERTAKINGS

Safety culture.

99. Undertakings shall promote a safety culture within its organisation.

Radiation Protection Programmes. *Amended by: L.N. 184 of 2020.*

100. (1) Undertakings shall establish a radiation protection programme.

The radiation protection programme may form part of the undertakings wider quality assurance programme.

(2) The radiation protection programme shall be:

(a) commensurate to the complexity and radiological safety and security risks;

(b) take into account the prior safety assessment pursuant to regulation 101;

(c) take into account all the relevant provisions of these regulations;

(d) documented;

(e) subject to periodic review by the undertaking;

(f) made available as appropriate to employees of the undertaking and

(g) made available at the request of the Secretariat.

(3) The radiation protection programme shall indicate the assignment of responsibilities of safety within the undertaking. The undertaking shall be able to demonstrate leadership in radiation safety matters at the highest levels in an organization.

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

Safety Assessments. *Amended by: L.N. 184 of 2020.*

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

(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.

(2) Before an undertaking commences a new practice or work activity in which no safety assessment has been made, a suitable and sufficient assessment shall be made.

(3) When carrying out safety assessments undertakings, shall give adequate consideration to:

(a) That prior to performing the assessment the undertaking shall have the necessary expertise and data available.

(b) The manner in which all practices that can effect workers and any other persons that give rise to radiation risks.

(c) That the primary purpose of the safety assessment is to:

(i) Determine whether there is an adequate level of radiation safety has or will be achieved.

(ii) Determine that the safety objectives established by the designer have been achieved.

(iii) Determine that the safety objectives of the undertakings have been achieved.

(iv) Determine that the operation is in compliance with the obligations on the undertaking as laid down in these regulations

(d) The assessment of the site characteristics.

(e) The identification and assessment of risks.

(f) The specification and assessment of safety functions.

(g) The determination of whether adequate safety measures are in place.

(h) The determination of the adequacy of engineering aspects.

(i) The assessment of how human interactions can effect safety.

(j) The assessment of safety over the lifetime of a facility or activity.

(k) If defense in depth is used, the assessment shall determine whether adequate provisions have been made at each of the levels of protection.

(l) If the facility or practise has different operational states, then the performance of the facility or activity needs to be assessed in the safety analysis, including, if necessary, the post-operational phase.

(m) Any calculation methods used in the safety analysis shall undergo verification and validation.

(4) Once the assessment is carried out:

(a) The results and findings of the safety assessment shall be documented.

(b) The undertaking shall consider the need to carry out an independent verification of the safety assessment before it is used by the operating organization or submitted to the Secretariat.

(c) The results of the safety assessment shall be used to specify the programme for maintenance, surveillance and inspection; to specify the procedures to be put in place for all operational activities significant to safety, and for responding to anticipated operational occurrences and accidents; to specify the necessary competences for the staff involved in the facility or activity; and to make decisions in an integrated, risk informed approach.

(d) The safety assessment shall be periodically reviewed and updated.

(5) Where the assessment made for the purposes of this regulation shows that a radiation risk to workers or other persons exists from an identifiable radiation accident, the undertaking shall take all reasonably practicable steps to-

(a) prevent any such accident;

(b) limit the consequences of any such accident which does occur; and

(c) provide workers with the appropriate information, instruction and training, and with the equipment necessary to restrict their exposure to ionising radiation.

(SECTION 2)

INSTITUTIONAL INFRASTRUCTURE

Recognition of services and experts.

102. (1) The Commission has the responsibility to recognize:

(a) occupational health services;

(b) dosimetry services;

(c) radiation protection experts;

(d) medical physics experts;

(e) training organizations or individuals referred to in regulation 14;

(f) technical service providers.

(2) Commission shall make available the criteria required for recognition for services or experts given in sub-regulation (1).

(3) Commission shall issue approval certificates for the entities referred to in sub-regulation (1) and approval certificates shall be time limited and may specify limitations.

(4) The Commission shall endeavour to ensure that the necessary arrangements are in place to ensure the continuity of expertise of these services and experts.

Occupational health services.

103. The Commission shall ensure that occupational health services perform medical surveillance of exposed workers, in accordance with Part VI, with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them involving work with ionising radiation.

Dosimetry services.

104. Dosimetry services shall determine internal or external doses to exposed workers subject to individual monitoring, in order to record the dose in cooperation with the undertaking and in the case of outside workers, the employer of the outside worker, and where relevant the occupational health service.

Radiation protection expert.
Amended by: L.N. 184 of 2020.

105. (1) A radiation protection expert is to give competent advice to the undertaking on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure.

(2) The advice of the radiation protection expert shall cover, where relevant, but not be limited to, the following:

(a) requirements of a radiation protection programme;

(b) development of safety culture;

(c) optimisation and establishment of appropriate dose constraints;

(d) plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;

(e) categorisation of controlled and supervised areas

(f) classification of workers;

(g) workplace and individual monitoring programmes and related personal dosimetry;

(h) appropriate radiation monitoring instrumentation;

(i) quality assurance;

(j) environmental monitoring programme;

(k) arrangements for radioactive waste management;

(l) arrangements for prevention of accidents and incidents;

(m) preparedness and response in emergency exposure situations;

(n) training and retraining programmes for exposed workers;

(o) investigation and analysis of accidents and incidents and appropriate remedial actions;

(p) employment conditions for pregnant and breastfeeding workers;

(q) preparation of appropriate documentation required under the radiation protection programme such as prior safety assessments and written procedures.

(3) The radiation protection expert shall, where appropriate, liaise with the medical physics expert.

(4) The radiation protection expert may be assigned by the

undertaking the performance of the tasks of radiation protection of workers and members of the public.

(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.

Radiation Protection Experts.

106. (1) Radiation protection experts need to be recognized by the Commission and will need to meet the following generic criteria:

(a) have a degree in radiography, medicine, or other physical science or a suitable combination of other qualifications and experience; and

(b) sufficient work experience directly concerned with radiation protection practice; and

(c) undertake continued professional development.

(2) The Commission shall issue detailed requirements for different applications based on the generic criteria given in the above.

(3) Radiation protection experts shall need re-certification by the Commission.

Medical physics experts.

107. (1) Medical physics experts are to act or give specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements set out in Part VII and in paragraph (b) of regulation 31(1).

(2) Depending on the medical radiological practice, the medical physics expert shall take responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:

(a) radiation protection programme;

(b) development of safety culture;

(c) optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;

(d) the definition and performance of quality assurance programmes of the medical radiological equipment;

(e) testing of medical radiological equipment;

(f) the preparation of technical specifications for medical radiological equipment and installation design;

(g) the surveillance of the medical radiological installations;

(h) the analysis of events involving, or potentially involving, accidental or unintended medical exposures;

(i) the selection of equipment required to perform radiation protection measurements;

(j) the training of practitioners and other staff in relevant aspects of radiation protection.

(3) The medical physics expert shall, where appropriate, liaise with the radiation protection expert.

Approval certificates.

108. The Commission shall issue approval certificates for medical physics experts for a validity period of not greater than a period of five years in a specialty (radiotherapy, nuclear medicine, diagnostic and interventional radiology)

Meetings.

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

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

(b) have attained European Qualifications Framework (EQF) Level 7 (ex: Master with 90-120 European Credit Transfer and Accumulation System (ECTS)); and

(c) two years structured accredited clinical training in Medical Physics in specialty (radiotherapy, nuclear medicine, diagnostic and interventional radiology); and

(d) two years documented full time work experience, within the preceding 28 months, in specialty (radiotherapy, nuclear medicine, diagnostic and interventional radiology) with documented CPD.

(2) Medical physics experts shall meet the following criteria for re-certification by the Commission:

(a) 48 months full time work experience in their specialty during the valid approval period, but not necessary 48 consecutive months.

(b) Documented CPD since the last certificate issued.

Radiation protection officer.

110. (1) All undertakings and employers of outside workers shall designate a radiation protection officer.

(2) Undertakings and employers of outside workers shall provide the radiation protection officers with the means necessary for them to carry out their tasks.

(3) The radiation protection officer shall report directly to the undertaking/and employers of outside workers.

(4) The undertaking is to ensure that the radiation protection officer has sufficient training.

Assistance.

111. (1) Radiation protection officers are to assist the undertaking in the execution of its radiation protection programme.

(2) The undertaking shall specify the specific roles of the radiation protection officer. The radiation protection officer may be assigned to perform aspects of the radiation protection programme or may have a supervisory role of some or all aspects of the programme.

(3) The task of the radiation protection officer may be carried out by a radiation protection unit established within an undertaking or by a radiation protection expert.

(SECTION 3)

CONTROL OF RADIOACTIVE SOURCES

General requirements for unsealed sources.

112. (1) The Secretariat shall specify in a license the arrangements for use of unsealed sources. The Secretariat shall specify in a separate discharge license conditions with regard to storage, disposal and discharge to the environment of unsealed sources.

(2) The undertaking shall, as appropriate and to the extent possible, keep records of unsealed sources under its responsibility, including location, transfer, disposal and discharge to the environment. The Secretariat shall require undertakings to notify it of discharges from its facility on an annual or more frequent basis, as specified in their appropriate license.

(3) Undertakings holding an unsealed radioactive source to notify the Secretariat promptly of any loss, theft, significant spill, or unauthorised use or release.

General requirements for sealed sources.

113. (1) The Secretariat shall specify in a license the arrangements for keeping control of sealed sources with regard to their location, use, storage and, when no longer required, their recycling or disposal.

(2) Undertakings shall keep records of all sealed sources under its responsibility, including location, transfer and disposal.

(3) Undertakings shall give the Secretariat 30 days notice of the intent to transfer any sealed source and shall not perform any

transfer until clearance is given by the Secretariat.

(4) Undertakings shall notify the Secretariat promptly of any loss, significant leakage, theft or unauthorised use of a sealed source.

Requirements for control of high-activity sealed sources. *Substituted by: L.N. 184 of 2020.*

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;

(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.

Record keeping by the undertaking.

115. (1) The undertaking shall keep records for high-activity sealed sources which shall include the information set out in the Thirteenth Schedule.

(2) The undertaking shall provide the Secretariat with an electronic or written copy of all relevant parts of the records referred to in sub-regulation (1):

(a) without undue delay, at the time of the establishment of such records, which should be as soon as possible after the source is acquired,

(b) by the 31st of January of every year,

(c) if the situation indicated on the information sheet has changed,

(d) without undue delay on the closure of the records for a specific source when the holder no longer holds this source; in this case the name of the holder or recognised installation to which the source is transferred shall be included,

(e) without undue delay on the closure of such records when the holder no longer holds any sources, and

(3) The undertaking's records shall be available for inspection by the Secretariat.

Control of high-activity sealed sources identification and marking.

116. (1) The manufacturer or supplier shall ensure that:

(a) Each high-activity sealed source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable.

The number shall also be engraved or stamped on the source container. If this is not feasible, or in the case of reusable transport containers, the source container shall, at least, bear information on the nature of the source.

(b) The source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard.

(2) The manufacturer shall provide a photograph of each

manufactured source design type and a photograph of the typical source container.

(3) The undertaking shall ensure that each high-activity sealed source is accompanied by written information indicating that the source is identified and marked in compliance with sub-regulation (1) and that the markings and labels referred to in sub-regulation (1) remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

(SECTION 4)

ORPHAN SOURCES

Detection of orphan sources.

117. (1) The Commission shall ensure that arrangements are made for:

(a) raising general awareness of the possible occurrence of orphan sources and associated hazards; and

(b) issuing guidance for persons who suspect or have knowledge of the presence of an orphan source and on the actions to be taken.

(2) The Commission shall encourage the establishment of systems aimed at detecting orphan sources at metal recycling installations, waste handling installations and at ports of entry to Malta

(3) The Secretariat shall provide specialised technical advice and assistance promptly to persons who suspect the presence of an orphan source and who are not normally involved in operations subject to radiation protection requirements.

Metal contamination.

118. (1) The Commission shall encourage the establishment of systems to detect the presence of radioactive contamination in metal products at Maltese ports.

(2) Scrap recycling installations and operators of monitoring equipment at ports shall promptly inform the Secretariat if they suspect or have knowledge of any contaminated material or radioactive source at their facility. Any contaminated material or radioactive source shall not be used, placed on the market, transported or disposed of without the involvement of the Secretariat.

Recovery, management, control and disposal of orphan sources.

119. (1) The national radiological emergency plan, as set out in regulation 122 shall include provisions for the assignment of responsibilities, to control and recover orphan sources and to deal with emergencies due to orphan sources.

(2) The Secretariat shall investigate as appropriate any past facilities that may have used sources that are not on the national

inventory of sources. Any orphan sources discovered shall be brought under regulatory control.

Financial security for orphan sources.

120. The Commission shall obtain the costs of recovering, managing, controlling and disposing of the sources from the government which may result from implementation of regulation 118.

(SECTION 5)

SIGNIFICANT EVENTS

Notification and recording of significant events.

121. Undertaking shall:

(a) implement, as appropriate, a recording and analysis system of significant events involving or potentially involving accidental or unintended exposures;

(b) promptly notify the Secretariat of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to occupational or public exposure or as defined by the Commission for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

National Emergency preparedness. *Amended by: L.N. 184 of 2020.*

122. (1) The Commission, shall, working closely with Civil Protection, develop emergency management systems. These systems shall be integrated in the national radiological emergency plan. The national radiological emergency plan shall include the elements listed in the Tenth Schedule.

(2) The national radiological emergency plan shall take into account the risks identified in the national radiological hazard assessment performed by the Commission.

(3) The national radiological emergency plan shall:

(a) have the objective of avoiding tissue reactions leading to severe deterministic effects in any individual from the affected population and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in Part III;

(b) include provision for the transition from an emergency exposure situation to an existing exposure situation;

(c) be tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national

and international level;

(d) where appropriate, incorporate relevant elements of the emergency management system referred to in regulation 122(1), 122(2);

(e) The national radiological emergency plan shall provide for the establishment of specific emergency response plans to address specific issues.

International cooperation.

123. (1) The Commission shall cooperate with other Member States and with third countries in addressing possible emergencies on its territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in those Member States or third countries.

(2) The Commission shall, in the event of an emergency occurring on its territory or likely to have radiological consequences on its territory, promptly establish contact with all other Member States and with third countries which may be involved or are likely to be affected with a view to sharing the assessment of the exposure situation and coordinating protective measures and public information by using, as appropriate, bilateral or international information exchange and coordination systems. These coordination activities shall not prevent or delay any necessary actions to be taken on a national level.

(3) The Commission shall promptly share information and cooperate with other relevant Member States, relevant third countries and relevant international organisations regarding the loss, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

(4) The Commission, where appropriate, cooperate with other Member States and with third countries in the transition from an emergency exposure situation to an existing exposure situation.

(5) The Secretariat, where appropriate, shall provide information to other Member States and with third countries of undeclared radioactive material detected at Maltese ports.

(SECTION 6)

EXISTING EXPOSURE SITUATIONS

Programmes on existing exposure situations.

124. (1) The Commission shall ensure that measures are taken, upon indication or evidence of exposures that cannot be disregarded from a radiation protection point of view, to identify and evaluate existing exposure situations taking into account the types of existing exposure situations listed in the Fifteenth Schedule, and to determine the corresponding occupational and public exposures.

(2) The Commission may decide, having regard to the general principle of justification, that an existing exposure situation warrants no consideration of protective or remedial measures.

(3) Existing exposure situations which are of concern from a radiation protection point of view and for which legal responsibility can be assigned shall be subject to the relevant requirements for planned exposure situations and accordingly such exposure situations shall be required to be notified as specified in regulation 34(4).

Establishment of strategies.

125. (1) The Commission shall arrange for the establishment of strategies to ensure the appropriate management of existing exposure situations commensurate with the risks and with the effectiveness of protective measures.

(2) Each strategy shall contain

(a) the objectives pursued;

(b) appropriate reference levels, taking into account the reference levels laid down in regulation 7.

Implementation of strategies.

126. (1) The Commission shall advice 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.

(2) The form, scale and duration of all protective measures considered for implementation of a strategy shall be optimised.

(3) The distribution of doses that has resulted from the implementation of a strategy shall be assessed. Further efforts shall be considered with the aim of optimising protection and reducing any exposures that are still above the reference level.

(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.

Radon action plan.

127. (1) In application of regulation 124(1) the Commission shall establish a national action plan addressing long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the issues set out in the Sixteenth Schedule and be updated on a regular basis.

(2) The Commission shall recommend to the Minister on appropriate measures to prevent radon ingress into new buildings. These measures may include specific requirements in national building codes.

(3) Commission shall identify areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant national reference level.

(SECTION 7)

SYSTEM OF ENFORCEMENT

Inspections.

128. (1) The Secretariat shall establish a system or systems of inspection to enforce the provisions adopted pursuant to these regulations and to initiate surveillance and corrective action where necessary.

(2) The Secretariat shall establish an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with the provisions adopted pursuant to these regulations.

(3) The Secretariat shall ensure that the findings from each inspection are recorded and communicated to the undertaking concerned. If the findings are related to an outside worker or workers, where appropriate, the findings shall also be communicated to the employer of the outside worker.

(4) The Secretariat shall ensure that outlines of the inspection programmes and the main findings from their implementation are available to the public.

(5) The Secretariat shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections

and from reported incidents and accidents and related findings.

.Enforcement.

129. Pursuant to the Act, the Secretariat has the power to require any individual or legal person to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the exposure situation is not in compliance with the provisions adopted pursuant to these regulations.

FIRST SCHEDULE
(Regulation 4)

Radiation and tissue weighting factors

A. Radiation weighting factors

Radiation type	W_R
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, E_n<1 MeV	$2.5 + 18.2e^{-[\ln(En)]^2/6}$
Neutrons, 1 MeV ≤ E_n≤50 MeV	$5.0 + 17.0\, e^{-[\ln(2\, En)]^2/6}$
Neutrons, E_n>50 MeV	$2.5 + 3.25\, e^{-[\ln(0.04\, En)]^2/6}$

Note: All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

B. Tissue weighting factors

Tissue	W_T
Bone-marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Breast	0.12
Remainder tissues (*)	0.12
Gonads	0.08
Bladder	0.04
Oesophagus	0.04
Liver	0.04
Thyroid	0.04
Bone surface	0.01
Brain	0.01
Salivary glands	0.01
Skin	0.01

(*) The W_T for the remainder tissues (0.12) applies to the arithmetic mean dose of the 13 organs and tissues for each sex listed below. Remainder tissues: adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

SECOND SCHEDULE

(Regulation 4)

Activity Of high-activity sealed sources and Security Values

For radionuclides not listed in the table below, the relevant activity is identical to the D-value defined in the IAEA publication Dangerous quantities of radioactive material (D-values), (EPR-D-VALUES 2006).

Table 1

	IAEA Code of Conduct on the safety and security of radioactive sources		
	Category 1	Category 2	Category 3
	Security Level A	Security Level B	Security Level C
	D x 1000 value	D x10 value	D Value
			Values defining high-activity sealed sources in this regulation
Radionuclide	Activity (TBq)	Activity (TBq)	Activity (TBq)
Am-241	6×10^{1}	6×10^{-1}	6×10^{-2}
Am-241/Be ([1])	6×10^{1}	6×10^{-1}	6×10^{-2}
Cf-252	2×10^{1}	2×10^{-1}	2×10^{-2}
Cm-244	5×10^{1}	5×10^{-1}	5×10^{-2}
Co-60	3×10^{1}	3×10^{-1}	3×10^{-2}
Cs-137	1×10^{2}	1×10^{0}	1×10^{-1}
Gd-153	1 x 103	1×10^{1}	1×10^{0}
Ir-192	8×10^{1}	8×10^{-1}	8×10^{-2}
Pm-147	4×10^{4}	4×10^{2}	4×10^{1}
Pu-238	6×10^{1}	6×10^{-1}	6×10^{-2}
Pu-239/Be	6×10^{1}	6×10^{-1}	6×10^{-2}
Ra-226	4×10^{1}	4×10^{-1}	4×10^{-2}
Se-75	2×10^{2}	2×10^{0}	2×10^{-1}
Sr-90 (Y-90)	1 x 103	1×10^{1}	1×10^{0}
Tm-170	2×10^{4}	2×10^{2}	2×10^{1}
Yb-169	3×10^{2}	$3x\ 10^{0}$	3×10^{-1}
Au-198	2×10^{2}	$2x\ 10^{0}$	2×10^{-1}
Cd-109	2×10^{4}	2×10^{2}	2×10^{1}
Co-57	7×10^{2}	7×10^{0}	7×10^{-1}
Fe-55	8 x 105	8 x 103	8×10^{2}
Ge-68	7×10^{2}	7×10^{0}	7×10^{-1}
Ni-63	6×10^{4}	6×10^{2}	6×10^{1}
Pd-103	9×10^{4}	9×10^{2}	9×10^{1}
Po-210	6×10^{1}	6×10^{-1}	6×10^{-2}
Ru-106	3×10^{2}	3×10^{0}	3×10^{-1}
Tl-204	2×10^{4}	2×10^{2}	2×10^{1}

([1]) The activity is that of the alpha-emitting radionuclide

THIRD SCHEDULE
(Regulation 27)

JUSTIFICATION OF NEW CLASSES OR TYPES OF PRACTICES INVOLVING CONSUMER PRODUCTS

(A) Any undertaking intending to manufacture or import into Malta consumer products for which the intended use is likely to lead to a new class or type of practice, shall provide the Commission with all relevant information, as to the:

(i) intended use of the product,

(ii) technical characteristics of the product;

(iii) in the case of products containing radioactive substances, information as to their means of fixation;

(iv) dose rates at relevant distances for the use of the product, including dose rates at a distance of 10cm from any accessible surface;

(v) expected doses to regular users of the product.

(B) The Commission shall examine that information and in particular assess whether:

(i) the performance of the consumer product justifies its intended use;

(ii) the design is adequate in order to minimize exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there should be conditions imposed on the technical and physical characteristics of the product;

(iii) the product is adequately designed to meet the exemption criteria, and, where applicable, is of an approved type and does not necessitate specific precautions for disposal when no longer in use;

(iv) the product is appropriately labelled and suitable documentation is provided to the consumer with instructions for proper use and disposal.

Amended by:
L.N. 184 of 2020.

FOURTH SCHEDULE
(Regulation 23)

LIST OF JUSTIFIABLE PRACTICES
INVOLVING IONIZING RADIATION

Pursuant to regulation 23 the following classes and types of practice resulting in exposure to ionising radiation that are deemed justified.

This list may be updated by the Commission, the updated list will be made publicly available by the Commission

1. Medical Exposures

(i) Diagnosis:

Use of ionising radiation in radiography, fluoroscopy, computed tomography, in-vivo nuclear and in-vitro nuclear medicine.

(ii) Therapy:

Use of ionising radiation in interventional radiology, in-vivo nuclear medicines, external beam radiotherapy, brachytherapy, radiography (for planning purposes) fluoroscopy (for planning purposes), computed tomography.

(iii) Health screening:

Use of ionising radiation in radiography and nuclear medicine.

2. Non-medical imaging exposure of humans

(i) Practices using medical radiological equipment:

(a) Radiological health assessment for employment purposes;

(b) Radiological health assessment for immigration purposes;

(c) Radiological health assessment for insurance purposes;

(d) Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc.;

(e) Radiological age assessment;

(f) Use of ionising radiation for the identification of concealed objects within the human body.

(ii) Practices not using medical radiological equipment:

(a) Use of ionising radiation for detection of concealed humans as part of cargo screening;

(b) Practices involving the use of ionising radiation for legal or security purposes.

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

3. Industrial

(i) Production of radioactive products:

Manufacture of radioisotopes using accelerators

(ii) Non-destructive testing

Use of radioactive sources, substances and radiation generators for radiography

(iii) Substance measurement and process control:

Use of sealed sources and x-ray generators for thickness gauging, density gauging, moisture Gauging, level gauging, flow measurement, borehole and well logging, control of pipeline crawlers

(iv) Detection and analysis:

(a) Use of sealed sources and x-ray generators for analysis

(b) Use of beta sources for gas chromatography detectors

(v) Elimination of static electricity:

Use of radioactive sources to eliminate static electricity

(vi) Illumination

(a) Use and repair of gaseous tritium light sources for illumination, in safety signs and equipment, sighting and location markers, watches and instruments.

(b) Use of radioluminous paint (tritium and promethium^{-1}47) for the luminising of timepieces and the repair of radioluminised timepieces.

(vii) Security screening

Use of x-rays, gamma rays to examine packages, baggage, containers or vehicles.

4. Other Practices

(i) Equipment producing ionising radiation incidentally

Use of electron beam welders, electron microscopes, radar, thermionic valves, cathode ray tubes, ion implantation machines and high voltage switchgear.

(ii) Radioactive tracers

Use of radioactive tracers for medical or biological techniques.

(iii) Medical and biomedical research

Use of ionising radiation in radiography, fluoroscopy, interventional radiography, computed tomography, in-vivo nuclear medicine, invitro nuclear medicine, teletherapy, brachytherapy and neutron analysis

(iv) Diagnosis – veterinary

Use of ionising radiation in radiography

(v) Transport of radioactive material

(vi) Safety devices

(vi) Import or export of equipment that can produce ionising radiation

Use of ionising radiation in smoke and fire detectors and other safety instruments

FIFTH SCHEDULE
(Regulation 33)

LIST OF INDUSTRIAL SECTORS INVOLVING NATURALLY-OCCURRING RADIOACTIVE MATERIAL

- Extraction of rare earths from monazite
- Production of thorium compounds and manufacture of thorium-containing products
- Processing of niobium/tantalum ore
- Oil and gas production
- Geothermal energy production
- TiO_2 pigment production
- Thermal phosphorus production
- Zircon and zirconium industry
- Production of phosphate fertilisers
- Cement production, maintenance of clinker ovens
- Coal-fired power plants, maintenance of boilers
- Phosphoric acid production
- Primary iron production
- Tin/lead/copper smelting
- Ground water filtration facilities
- Mining of ores other than uranium ore

SIXTH SCHEDULE
(Regulation 35 and 39)

EXEMPTION AND CLEARANCE CRITERIA

1. Exemption

Practices may be exempted from notification either directly, on the basis of compliance with exemption levels (activity values (in Bq) or activity concentration values (in kBq kg^{-1})) laid down in section 2, or on the basis of higher values that, for specific applications, are established by the Commission, satisfying the general exemption and clearance criteria set out in section 3. Practices subject to notification may be exempted from authorisation by law or general administrative act, or through an ad-hoc regulatory decision, on the basis of the information provided in conjunction with the notification of the practice and in line with general exemption criteria set out in section 3.

2. Exemption and clearance levels

(a) The total activity values (in Bq) for exemption apply to the total activity involved in a practice and are laid down in column 3 of Table B for artificial radionuclides and for some naturally-occurring radionuclides used in consumer products. For other practices involving naturally-occurring radionuclides, such values are, in general, not applicable

(b) The exempt activity concentration values (in kBq kg^{-1}) for the materials involved in the practice are laid down in Table A, Part 1, for artificial radionuclides, and in Table A, Part 2, for naturally-occurring radionuclides. The values in Table A, Part 1, are given for individual radionuclides, where applicable, including short-lived radionuclides in equilibrium with the parent nuclide, as indicated. The values in Table A, Part 2, apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain, which are not in equilibrium with the parent radionuclide, higher values may be applied

(c) The concentration values in Table A, Part 1, or in Table A, Part 2, also apply to the clearance of solid materials for reuse, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking Community guidance into account, including, where appropriate, additional requirements, in terms of surface activity or monitoring requirements

(d) For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate, this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Table A, Part 2, apply individually to

each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of higher values taking Community guidance into account.

(e) The values in Table A, Part 2, may not be used to exempt the incorporation into building materials of residues from industries processing naturally-occurring radioactive material. For this purpose, compliance with the provisions of regulation 98 shall be verified. The values laid down in Table B, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the Commission may apply these values to smaller entities or packages, for instance to exempt the transport or storage of exempted consumer products, if the general exemption criteria in section 3 are satisfied.

(3) General exemption and clearance criteria

(a) The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows

(i) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and

(ii) the type of practice has been determined to be justified; and

(iii) the practice is inherently safe

(b) Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Table A or Table B are deemed to fulfil criterion (iii).

(c) Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1, or Table B, are deemed to comply with criterion (i) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water

(d) In the case of moderate amounts of material, as specified by Commission for specific types of practice, the activity concentration values laid down in Table B, column 2, may be used instead of the values laid down in Table A, Part 1, for the purpose of exemption from authorisation.

(e) For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A or Table B, an assessment shall be made in the light of the general criteria (i) to (iii) above. For compliance with the general criterion (i), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:

- For artificial radionuclides:

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 μSv or less in a year.

- For naturally-occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. The Commission may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

For the purpose of exemption from authorisation, less restrictive dose criteria may be applied.

TABLE A

Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material

TABLE A

PART 1

Artificial radionuclides

Radionuclide	Activity concentration (kBq kg^{-1})	Radionuclide	Activity concentration (kBq kg^{-1})	Radionuclide	Activity concentration (kBq kg^{-1})
H-3	100	Co-55	10	Sr-91 ([a])	10
Be-7	10	Co-56	0.1	Sr-92	10
C-14	1	Co-57	1	Y-90	1 000
F-18	10	Co-58	1	Y-91	100
Na-22	0.1	Co-58m	10 000	Y-91m	100
Na-24	1	Co-60	0.1	Y-92	100
Si-31	1 000	Co-60m	1 000	Y-93	100
P-32	1 000	Co-61	100	Zr-93	10
P-33	1 000	Co-62m	10	Zr-95 ([a])	1
S-35	100	Ni-59	100	Zr-97 ([a])	10
Cl-36	1	Ni-63	100	Nb-93m	10
Cl-38	10	Ni-65	10	Nb-94	0.1
K-42	100	Cu-64	100	Nb-95	1
K-43	10	Zn-65	0.1	Nb-97 ([a])	10
Ca-45	100	Zn-69	1 000	Nb-98	10
Ca-47	10	Zn-69m ([a])	10	Mo-90	10
Sc-46	0.1	Ga-72	10	Mo-93	10
Sc-47	100	Ge-71	10 000	Mo-99 ([a])	10
Sc-48	1	As-73	1 000	Mo-101 ([a])	10
V-48	1	As-74	10	Tc-96	1
Cr-51	100	As-76	10	Tc-96m	1 000
Mn-51	10	As-77	1 000	Tc-97	10
Mn-52	1	Se-75	1	Tc-97m	100

Radionuclide	Activity concentration ($kBq\ kg^{-1}$)
Mn-52m	10
Mn-53	100
Mn-54	0.1
Mn-56	10
Fe-52 ([a])	10
Fe-55	1 000
Fe-59	1
Rh-105	100
Pd-103 ([a])	1 000
Pd-109 ([a])	100
Ag-105	1
Ag-110m ([a])	0.1
Ag-111	100
Cd-109 ([a])	1
Cd-115 ([a])	10
Cd-115m ([a])	100
In-111	10
In-113m	100
In-114m ([a])	10
In-115m	100
Sn-113 ([a])	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125 ([a])	0.1
Te-123m	1
Te-125m	1 000
Te-127	1 000
Te-127m ([a])	10
Te-129	100
Te-129m ([a])	10
Te-131	100
Te-131m ([a])	10
Te-132 ([a])	1
Te-133	10
Te-133m	10
Te-134	10
Os-193	100
Ir-190	1

Radionuclide	Activity concentration ($kBq\ kg^{-1}$)
Br-82	1
Rb-86	100
Sr-85	1
Sr-85m	100
Sr-87m	100
Sr-89	1 000
Sr-90 ([a])	1
I-123	100
I-125	100
I-126	10
I-129	0.01
I-130	10
I-131	10
I-132	10
I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1 000
Cs-132	10
Cs-134	0,1
Cs-134m	1 000
Cs-135	100
Cs-136	1
Cs-137 ([a])	0.1
Cs-138	10
Ba-131	10
Ba-140	1
La-140	1
Ce-139	1
Ce-141	100
Ce-143	10
Ce-144	10
Pr-142	100
Pr-143	1 000
Nd-147	100
Nd-149	100
U-230	10
U-231 ([a])	100

Radionuclide	Activity concentration ($kBq\ kg^{-1}$)
Tc-99	1
Tc-99m	100
Ru-97	10
Ru-103 ([a])	1
Ru-105 ([a])	10
Ru-106 ([a])	0.1
Rh-103m	10 000
Pm-147	1 000
Pm-149	1 000
Sm-151	1 000
Sm-153	100
Eu-152	0 1
Eu-152m	100
Eu-154	0 1
Eu-155	1
Gd-153	10
Gd-159	100
Tb-160	1
Dy-165	1 000
Dy-166	100
Ho-166	100
Er-169	1 000
Er-171	100
Tm-170	100
Tm-171	1 000
Yb-175	100
Lu-177	100
Hf-181	1
Ta-182	0 1
W-181	10
W-185	1 000
W-187	10
Re-186	1 000
Re-188	100
Os-185	1
Os-191	100
Os-191m	1 000
Cm-246	0.1
Cm-247 ([a])	0.1

Radionuclide	Activity concentration (kBq kg^{-1})
Ir-192	1
Ir-194	100
Pt-191	10
Pt-193m	1 000
Pt-197	1 000
Pt-197m	100
Au-198	10
Au-199	100
Hg-197	100
Hg-197m	100
Hg-203	10
Tl-200	10
Tl-201	100
Tl-202	10
Tl-204	1
Pb-203	10
Bi-206	1
Bi-207	0.1
Po-203	10
Po-205	10
Po-207	10
At-211	1 000
Ra-225	10
Ra-227	100
Th-226	1 000
Th-229	0.1
Pa-230	10
Pa-233	10

Radionuclide	Activity concentration (kBq kg^{-1})
U-232 ([a])	0.1
U-233	1
U-236	10
U-237	100
U-239	100
U-240 ([a])	100
Np-237 ([a])	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0.1
Pu-239	0.1
Pu-240	0.1
Pu-241	10
Pu-242	0,1
Pu-243	1 000
Pu-244 ([a])	0.1
Am-241	0.1
Am-242	1 000
Am-242 ([a])	0.1
Am-243 ([a])	0.1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0.1

Radionuclide	Activity concentration (kBq kg^{-1})
Cm-248	0.1
Bk-249	100
Cf-246	1 000
Cf-248	1
Cf-249	0.1
Cf-250	1
Cf-251	0.1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254 ([a])	0.1
Es-254m ([a])	10
Fm-254	10 000
Fm-255	100

([a]) Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following table.

Parent Radionuclide	Progeny	Parent Radionuclide	Progeny	Parent Radionuclide	Progeny
Fe-52	Mn-52m	Pd-103	Rh-103m	Te132	I-132
Zn-69m	Zn-69	Pd-109	Ag-109m	Cs-137	Ba-137m
Sr-90	Y-90	Ag-110m	Ag-110	Ce-144	Pr-144, Pr-144m Pr-144m
Sr-91	Y-91m	Cd-109	Ag-109m	U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
Zr-95	Nb-95	Cd-115	In-115m	U-240	Np-240m, Np-240
Zr-97	Nb-97m, Nb-97	Cd-115m	In-115m	Np237	Pa-233
Nb-97	Nb-97m	In-114m	In-114	Pu-244	U-240, Np-240m, Np-240
Mo-99	Tc-99m	Sn-113	In-113m	Am-242m	Np-238
Mo-101	Tc-101	Sb-125	Te-125m	Am-243	Np-239
Ru-103	Rh-103m	Te-127m	Te-127	Cm-247	Pu-243
Ru-105	Rh-105m	Te-129m	Te-129	Es-254	Bk-250
Ru-106	Rh-106	Te-131m	Te-131	Es-254m	Fm-254

For radionuclides not listed in Table A, Part 1 the Commission shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A, Part 1

TABLE A PART 2

Naturally occurring radionuclides

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny:

Natural radionuclides from the U-238 series	1 kBq kg^{-1}
Natural radionuclides from the Th-232 series	1 kBq kg^{-1}

K-40	10 kBq kg^{-1}

TABLE B

Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2)

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)	Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
H-3	$1x10^6$	$1x10^9$	Mn-56	$1x10^1$	$1x10^5$
Be-7	$1x10^3$	$1x10^7$	Fe-52	$1x10^1$	$1x10^6$
C-14	$1x10^4$	$1x10^7$	Fe-55	$1x10^4$	$1x10^6$
O-15	$1x10^2$	$1x10^9$	Fe-59	$1x10^1$	$1x10^6$
F-18	$1x10^1$	$1x10^6$	Co-55	$1x10^1$	$1x10^6$
Na-22	$1x10^1$	$1x10^6$	Co-56	$1x10^1$	$1x10^5$
Na-24	$1x10^1$	$1x10^5$	Co-57	$1x10^2$	$1x10^6$
Si-31	$1x10^3$	$1x10^6$	Co-58	$1x10^1$	$1x10^6$
P-32	$1x10^3$	$1x10^5$	Co-58m	$1x10^4$	$1x10^7$
P-33	$1x10^5$	$1x10^8$	Co-60	$1x10^1$	$1x10^5$
S-35	$1x10^5$	$1x10^8$	Co-60m	$1x10^3$	$1x10^6$
Cl-36	$1x10^4$	$1x10^6$	Co-61	$1x10^2$	$1x10^6$
Cl-38	$1x10^1$	$1x10^5$	Co-62m	$1x10^1$	$1x10^5$
Ar-37	$1x10^6$	$1x10^8$	Ni-59	$1x10^4$	$1x10^8$
Ar-41	$1x10^2$	$1x10^9$	Ni-63	$1x10^5$	$1x10^8$
K-40 ([1])	$1x10^2$	$1x10^6$	Ni-65	$1x10^1$	$1x10^6$
K-42	$1x10^2$	$1x10^6$	Cu-64	$1x10^2$	$1x10^6$
K-43	$1x10^1$	$1x10^6$	Zn-65	$1x10^1$	$1x10^6$
Ca-45	$1x10^4$	$1x10^7$	Zn-69	$1x10^4$	$1x10^6$
Ca-47	$1x10^1$	$1x10^6$	Zn-69m	$1x10^2$	$1x10^6$
Sc-46	$1x10^1$	$1x10^6$	Ga-72	$1x10^1$	$1x10^5$
Sc-47	$1x10^2$	$1x10^6$	Ge-71	$1x10^4$	$1x10^8$
Sc-48	$1x10^1$	$1x10^5$	As-73	$1x10^3$	$1x10^7$
V-48	$1x10^1$	$1x10^5$	As-74	$1x10^1$	$1x10^6$
Cr-51	$1x10^3$	$1x10^7$	As-76	$1x10^2$	$1x10^5$

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
Mn-51	$1x10^{1}$	$1x10^{5}$
Mn-52	$1x10^{1}$	$1x10^{5}$
Mn-52m	$1x10^{1}$	$1x10^{5}$
Mn-53	$1x10^{4}$	$1x10^{9}$
Mn-54	$1x10^{1}$	$1x10^{6}$
Kr-77	$1x10^{2}$	$1x10^{9}$
Kr-79	$1x10^{3}$	$1x10^{5}$
Kr-81	$1x10^{4}$	$1x10^{7}$
Kr-83m	$1x10^{5}$	$1x10^{12}$
Kr-85	$1x10^{5}$	$1x10^{4}$
Kr-85m	$1x10^{3}$	$1x10^{10}$
Kr-87	$1x10^{2}$	$1x10^{9}$
Kr-88	$1x10^{2}$	$1x10^{9}$
Rb-86	$1x10^{2}$	$1x10^{5}$
Sr-85	$1x10^{2}$	$1x10^{6}$
Sr-85m	$1x10^{2}$	$1x10^{7}$
Sr-87m	$1x10^{2}$	$1x10^{6}$
Sr-89	$1x10^{3}$	$1x10^{6}$
Sr-90 ([b])	$1x10^{2}$	$1x10^{4}$
Sr-91	$1x10^{1}$	$1x10^{5}$
Sr-92	$1x10^{1}$	$1x10^{6}$
Y-90	$1x10^{3}$	$1x10^{5}$
Y-91	$1x10^{3}$	$1x10^{6}$
Y-91m	$1x10^{2}$	$1x10^{6}$
Y-92	$1x10^{2}$	$1x10^{5}$
Y-93	$1x10^{2}$	$1x10^{5}$
Zr-93([b])	$1x10^{3}$	$1x10^{7}$
Zr-95	$1x10^{1}$	$1x10^{6}$
Zr-97([b])	$1x10^{1}$	$1x10^{5}$
Nb-93m	$1x10^{4}$	$1x10^{7}$
Nb-94	$1x10^{1}$	$1x10^{6}$
Nb-95	$1x10^{1}$	$1x10^{6}$
Nb-97	$1x10^{1}$	$1x10^{6}$
Nb-98	$1x10^{1}$	$1x10^{5}$
Mo-90	$1x10^{1}$	$1x10^{6}$
Sb-122	$1x10^{2}$	$1x10^{4}$

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
As-77	$1x10^{3}$	$1x10^{6}$
Se-75	$1x10^{2}$	$1x10^{6}$
Br-82	$1x10^{1}$	$1x10^{6}$
Kr-74	$1x10^{2}$	$1x10^{9}$
Kr-76	$1x10^{2}$	$1x10^{9}$
Mo-93	$1x10^{3}$	$1x10^{8}$
Mo-99	$1x10^{2}$	$1x10^{6}$
Mo-101	$1x10^{1}$	$1x10^{6}$
Tc-96	$1x10^{1}$	$1x10^{6}$
Tc-96m	$1x10^{3}$	$1x10^{7}$
Tc-97	$1x10^{3}$	$1x10^{8}$
Tc-97m	$1x10^{3}$	$1x10^{7}$
Tc-99	$1x10^{4}$	$1x10^{7}$
Tc-99m	$1x10^{2}$	$1x10^{7}$
Ru-97	$1x10^{2}$	$1x10^{7}$
Ru-103	$1x10^{2}$	$1x10^{6}$
Ru-105	$1x10^{1}$	$1x10^{6}$
Ru-106([b])	$1x10^{2}$	$1x10^{5}$
Rh-103m	$1x10^{4}$	$1x10^{8}$
Rh-105	$1x10^{2}$	$1x10^{7}$
Pd-103	$1x10^{3}$	$1x10^{8}$
Pd-109	$1x10^{3}$	$1x10^{6}$
Ag-105	$1x10^{2}$	$1x10^{6}$
Ag-108m	$1x10^{1}$	$1x10^{6}$
Ag-110m	$1x10^{1}$	$1x10^{6}$
Ag-111	$1x10^{3}$	$1x10^{6}$
Cd-109	$1x10^{4}$	$1x10^{6}$
Cd-115	$1x10^{2}$	$1x10^{6}$
Cd-115m	$1x10^{3}$	$1x10^{6}$
In-111	$1x10^{2}$	$1x10^{6}$
In-113m	$1x10^{2}$	$1x10^{6}$
In-114m	$1x10^{2}$	$1x10^{6}$
In-115m	$1x10^{2}$	$1x10^{6}$
Sn-113	$1x10^{3}$	$1x10^{7}$
Sn-125	$1x10^{2}$	$1x10^{5}$
Cs-132	$1x10^{1}$	$1x10^{5}$

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
Sb-124	$1x10^1$	$1x10^6$
Sb-125	$1x10^2$	$1x10^6$
Te-123m	$1x10^2$	$1x10^7$
Te-125m	$1x10^3$	$1x10^7$
Te-127	$1x10^3$	$1x10^6$
Te-127m	$1x10^3$	$1x10^7$
Te-129	$1x10^2$	$1x10^6$
Te-129m	$1x10^3$	$1x10^6$
Te-131	$1x10^2$	$1x10^5$
Te-131m	$1x10^1$	$1x10^6$
Te-132	$1x10^2$	$1x10^7$
Te-133	$1x10^1$	$1x10^5$
Te-133m	$1x10^1$	$1x10^5$
Te-134	$1x10^1$	$1x10^6$
I-123	$1x10^2$	$1x10^7$
I-125	$1x10^3$	$1x10^6$
I-126	$1x10^2$	$1x10^6$
I-129	$1x10^2$	$1x10^5$
I-130	$1x10^1$	$1x10^6$
I-131	$1x10^2$	$1x10^6$
I-132	$1x10^1$	$1x10^5$
I-133	$1x10^1$	$1x10^6$
I-134	$1x10^1$	$1x10^5$
I-135	$1x10^1$	$1x10^6$
Xe-131m	$1x10^4$	$1x10^4$
Xe-133	$1x10^3$	$1x10^4$
Xe-135	$1x10^3$	$1x10^{10}$
Cs-129	$1x10^2$	$1x10^5$
Cs-131	$1x10^3$	$1x10^6$
Dy-166	$1x10^3$	$1x10^6$
Ho-166	$1x10^3$	$1x10^5$
Er-169	$1x10^4$	$1x10^7$
Er-171	$1x10^2$	$1x10^6$
Tm-170	$1x10^3$	$1x10^6$
Tm-171	$1x10^4$	$1x10^8$
Yb-175	$1x10^3$	$1x10^7$

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
Cs-134m	$1x10^3$	$1x10^5$
Cs-134	$1x10^1$	$1x10^4$
Cs-135	$1x10^4$	$1x10^7$
Cs-136	$1x10^1$	$1x10^5$
Cs-137([b])	$1x10^1$	$1x10^4$
Cs-138	$1x10^1$	$1x10^4$
Ba-131	$1x10^2$	$1x10^6$
Ba-140([b])	$1x10^1$	$1x10^5$
La-140	$1x10^1$	$1x10^5$
Ce-139	$1x10^2$	$1x10^6$
Ce-141	$1x10^2$	$1x10^7$
Ce-143	$1x10^2$	$1x10^6$
Ce-144([b])	$1x10^2$	$1x10^5$
Pr-142	$1x10^2$	$1x10^5$
Pr-143	$1x10^4$	$1x10^6$
Nd-147	$1x10^2$	$1x10^6$
Nd-149	$1x10^2$	$1x10^6$
Pm-147	$1x10^4$	$1x10^7$
Pm-149	$1x10^3$	$1x10^6$
Sm-151	$1x10^4$	$1x10^8$
Sm-153	$1x10^2$	$1x10^6$
Eu-152	$1x10^1$	$1x10^6$
Eu-152m	$1x10^2$	$1x10^6$
Eu-154	$1x10^1$	$1x10^6$
Eu-155	$1x10^2$	$1x10^7$
Gd-153	$1x10^2$	$1x10^7$
Gd-159	$1x10^3$	$1x10^6$
Tb-160	$1x10^1$	$1x10^6$
Dy-165	$1x10^3$	$1x10^6$
Hg-203	$1x10^2$	$1x10^5$
Tl-200	$1x10^1$	$1x10^6$
Tl-201	$1x10^2$	$1x10^6$
Tl-202	$1x10^2$	$1x10^6$
Tl-204	$1x10^4$	$1x10^4$
Pb-203	$1x10^2$	$1x10^6$
Pb-210([b])	$1x10^1$	$1x10^4$

Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)	Radionuclide	Activity concentration (kBq kg^{-1})	Activity (Bq)
Lu-177	$1x10^3$	$1x10^7$	Pb-212([b])	$1x10^1$	$1x10^5$
Hf-181	$1x10^1$	$1x10^6$	Bi-206	$1x10^1$	$1x10^5$
Ta-182	$1x10^1$	$1x10^4$	Bi-207	$1x10^1$	$1x10^6$
W-181	$1x10^3$	$1x10^7$	Bi-210	$1x10^3$	$1x10^6$
W-185	$1x10^4$	$1x10^7$	Bi-212([b])	$1x10^1$	$1x10^5$
W-187	$1x10^2$	$1x10^6$	Po-203	$1x10^1$	$1x10^6$
Re-186	$1x10^3$	$1x10^6$	Po-205	$1x10^1$	$1x10^6$
Re-188	$1x10^2$	$1x10^5$	Po-207	$1x10^1$	$1x10^6$
Os-185	$1x10^1$	$1x10^6$	Po-210	$1x10^1$	$1x10^4$
Os-191	$1x10^2$	$1x10^7$	At-211	$1x10^3$	$1x10^7$
Os-191m	$1x10^3$	$1x10^7$	Rn-220([b])	$1x10^4$	$1x10^7$
Os-193	$1x10^2$	$1x10^6$	Rn-222([b])	$1x10^1$	$1x10^8$
Ir-190	$1x10^1$	$1x10^6$	Ra-223([b])	$1x10^2$	$1x10^5$
Ir-192	$1x10^1$	$1x10^4$	Ra-224([b])	$1x10^1$	$1x10^5$
Ir-194	$1x10^2$	$1x10^5$	Ra-225	$1x10^2$	$1x10^5$
Pt-191	$1x10^2$	$1x10^6$	Ra-226([b])	$1x10^1$	$1x10^4$
Pt-193m	$1x10^3$	$1x10^7$	Ra-227	$1x10^2$	$1x10^6$
Pt-197	$1x10^3$	$1x10^6$	Ra-228([b])	$1x10^1$	$1x10^5$
Pt-197m	$1x10^2$	$1x10^6$	Ac-228	$1x10^1$	$1x10^6$
Au-198	$1x10^2$	$1x10^6$	Th-226([b])	$1x10^3$	$1x10^7$
Au-199	$1x10^2$	$1x10^6$	Th-227	$1x10^1$	$1x10^4$
Hg-197	$1x10^2$	$1x10^7$	Th-228([b])	$1x10^0$	$1x10^4$
Hg-197m	$1x10^2$	$1x10^6$	Th-229([b])	$1x10^0$	$1x10^3$

(b) http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2014:013:FULL&from=EN - ntr3-L_2014013EN.01004501-E0003

SEVENTH SCHEDULE
(Regulation 98)

DEFINITION AND USE OF THE ACTIVITY CONCENTRATION INDEX FOR THE GAMMA RADIATION EMITTED BY BUILDING MATERIALS

For the purposes of regulation 98(2),for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

The activity concentration index I is given by the following formula:

$I = C_{Ra226}/300\ Bq/kg + C_{Th232}/200\ Bq/kg + C_{K40}/3000\ Bq/kg$

where C_{Ra226}, C_{Th232} and C_{K40} are the activity concentrations in Bq/kg of the corresponding radionuclides in the building material.

The index relates to the gamma radiation dose, in excess of typical outdoor exposure, in a building constructed from a specified building material. The index applies to the building material, not to its constituents except when those constituents are building materials themselves and are separately assessed as such. For application of the index to such constituents, in particular residues from industries processing naturally-occurring radioactive material recycled into building materials, an appropriate partitioning factor needs to be applied. The activity concentration index value of 1 can be used as a conservative screening tool for identifying materials that may cause the reference level laid down in regulation 98(1) to be exceeded. The calculation of dose needs to take into account other factors such as density, thickness of the material as well as factors relating to the type of building and the intended use of the material (bulk or superficial).

EIGHTH SCHEDULE
(Regulation 38)

LIST OF INFORMATION FOR LICENCE APPLICATIONS

(a) Responsibilities and organisational arrangements for protection and safety

(b) Staff competences, including information and training

(c) Design features of the facility and of radiation sources

(d) Anticipated occupational and public exposures in normal operation

(e) Safety assessment of the activities and the facility.

(f) Emergency procedures.

(g) Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

(h) Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements

(i) Management of disused sources.

(j) Quality assurance programmes.

NINTH SCHEDULE
(Regulation 52)

DATA SYSTEM FOR INDIVIDUAL RADIOLOGICAL MONITORING

(1) Individual monitoring data to be kept by the undertaking/employer of outside worker for exposed workers:

(a) Surname

(b) First Name

(c) Maltese ID number or other overseas unique personal ID

(d) Sex

(e) Date of Birth

(f) Nationality

(g) Categorisation of the worker in accordance with regulation 49

(h) Particulars of any Medical surveillance required under the regulations

(i) Results of individual monitoring of the exposed worker pursuant to regulations 50, 51, 61, 62, 63 and, if decided by the Commission pursuant to regulations 44(2), 64(3)

(j) The starting date of individual monitoring and where available the end date

(k) Data on the undertaking, including the name, address, Commission reference number for undertaking.

(2) Data to be sent in the form of an annual return to the Secretariat.

The Secretariat will specify the format in which the data is to be sent.

(a) Name of the undertaking/employer of the outside worker

(b) Report year

(c) Dosimetry service provider and any local agents for dosimetry service provider

(d) Surname

(e) First Name

(f) Maltese ID number or other overseas unique personal ID

(g) Categorisation of the worker in accordance with regulation 49

(h) Results of individual monitoring of the exposed worker

(3) Data on outside workers to be supplied to an undertaking.

(a) Name of the employer of the outside worker

(b) Name of the undertaking owning the controlled area

(c) Start date of work in the undertaking's controlled area

(d) End date of work in the undertaking's controlled area

(e) Surname

(f) First Name

(g) Maltese ID number or other overseas unique personal ID

(h) Nationality

(i) Categorisation of the worker in accordance with regulation 49

(j) Particulars of any Medical surveillance required under the regulations and if the worker is classed fit, fit subject to conditions or unfit.

(k) Any restrictions of working with ionizing radiation and if so specify them

(l) Date of last periodic health review and the period of the validity of result

(m) Results of individual monitoring of the exposed worker over the preceding 5 year period.

Amended by:
L.N. 184 of 2020.

TENTH SCHEDULE
(Regulation 91 and 122)

EMERGENCY MANAGEMENT SYSTEMS
AND EMERGENCY RESPONSE PLANS

A. Elements to be included in an emergency management system

(1) Assessment of potential emergency exposure situations and associated public and emergency occupational exposures;

(2) Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements;

(3) Establishment of emergency response plans at appropriate levels and related to a specific facility or human activity;

(4) Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and at appropriate national and international levels;

(5) Health protection of emergency workers;

(6) Arrangements for the provision of prior information and training for emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises;

(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.

B. Elements to be included in an emergency response plan

For emergency preparedness:

(1) Reference levels for public exposure, taking into account the criteria laid down in regulation 7

(2) Reference levels for emergency occupational exposure taking into account regulation 63

(3) Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;

(4) Predefined generic criteria for particular protective measures;

(5) Default triggers or operational criteria such as observables and indicators of on-scene conditions;

(6) Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other Member States and with third countries which may be involved or are likely to be affected;

(7) Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

For emergency response:

The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:

(1) Promptly implementing protective measures, if possible, before any exposure occurs;

(2) Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;

(3) Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;

(4) Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

Amended by:
L.N. 184 of 2020.

ELEVENTH SCHEDULE
(Regulation 93 and 94)

INFORMATION TO MEMBERS OF THE PUBLIC ABOUT HEALTH PROTECTION MEASURES TO BE APPLIED AND STEPS TO BE TAKEN IN THE EVENT OF AN EMERGENCY

A. Prior information to the members of the public likely to be affected by an emergency

(1) Basic facts about radioactivity and its effects on human beings and on the environment;

(2) The various types of emergency covered and their consequences for the public and the environment;

(3) Emergency measures envisaged to alert, protect and assist the public in the event of an emergency.

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

B. Information to be provided to the affected members of the public in the event of an emergency

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

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

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

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

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

(c) announcements recommending cooperation with instructions or requests by the competent authority.

(2) If the emergency is preceded by a pre-alarm phase, the members of the public likely to be affected shall already receive information and advice during that phase, such as:

(a) an invitation to the members of the public concerned to tune in to relevant communication channels;

(b) preparatory advice to establishments with particular collective responsibilities;

(c) recommendations to occupational groups particularly affected.

(3) This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

TWELFTH SCHEDULE
(Regulation 98)

INDICATIVE LIST OF TYPES OF BUILDING MATERIALS CONSIDERED WITH REGARD TO THEIR EMITTED GAMMA RADIATION

1. Natural materials

(a) Alum-shale.

- Building materials or additives of natural igneous origin, such as:
- granitoides (such as granites, syenite and orthogneiss),
- porphyries;
- tuff;
- pozzolana (pozzolanic ash);
- lava.

2. Materials incorporating residues from industries processing naturally-occurring radioactive material, such as:

- fly ash;
- phosphogypsum;
- phosphorus slag;
- tin slag;
- copper slag;
- red mud (residue from aluminium production);
- residues from steel production

THIRTEENTH SCHEDULE
(Regulation 115)

<table>
<tr><td colspan="3">STANDARD RECORD SHEET FOR HIGH-ACTIVITY SEALED SOURCES (HASS)
(optional in italics)</td></tr>
<tr><td>1. HASS identification number

Manufacturer device number:

Field of use:</td><td>2. Identification of the licensed undertaking
Name:
Address:

Country:
Manufacturer □ Supplier □ User□</td><td>3. Location of HASS if not the same as in 2
Name:
Address:

Country:
Fixed use □ Storage □ Mobile use□</td></tr>
<tr><td>4. Recording

Date of start of recording:
Date of transfer of records to historic file:</td><td>5. Licence

Number:
Date of issue:

Date of expiry:</td><td>6. Operational controls of HASS

Date:
Date:

Date:
Date:
Date:
Date:
Date:
Date:
Date:</td></tr>
<tr><td>7. HASS characteristics
Year of manufacture
Radionuclide:
Activity at the date of manufacturing:
Activity reference date:
Manufacturer/Supplier (*):
Name:
Address:

Country:
Physical and chemical characteristics
Source type Identification
Capsule identification
ISO classification
ANSI classification
IAEA source category
Neutron source Yes□ No□</td><td>8. Receipt of HASS
Date of Receipt:
Receipt from:
Name:

Address:

Country:
Manufacturer □ Supplier □ User□

9. Transfer of HASS
Date of transfer:
Name:

Address:

Country:
Licence Number:
Date of issue:
Date of expiry:</td><td>10. Further information
Loss □ Date of Loss:
Theft □ Date of theft:

Findings: Yes□ No □

Date:
Place:
Other information:</td></tr>
</table>

Neutron source target: Neutron flux:	Manufacturer □ Supplier □ Other undertaking □ Facility for long term storage or disposal □	

(*)Where the manufacturer of the source is established outside the community the name and address of the importer-supplier may be provide instead

FOURTEENTH SCHEDULE
(Regulation 114)

SECURITY MEASURES FOR HIGH ACTIVITY SOURCES

Table1 Type of security measures required

<table>
<tr><th>Security Level
C Sources</th><th>Security Level
B Sources</th><th>Security Level
A Sources</th></tr>
<tr><td colspan="3">Safe management and protect as an asset</td></tr>
<tr><td colspan="3">Deter unauthorised access</td></tr>
<tr><td rowspan="3"></td><td colspan="2">Timely detection of unauthorised access</td></tr>
<tr><td colspan="2">Timely detection of unauthorised acquisition</td></tr>
<tr><td>Delay acquisition until response is possible</td></tr>
</table>

Administrative Measures

Holders should have the following administrative procedures in order to comply with these regulations

- access control procedures;
- key control procedures;
- adequate surveillance for activity levels 1 & 2;
- records related to management of sources;
- inventories;
- reliability and trustworthiness of personnel;
- information security for activity levels 1 & 2;
- quality assurance measures; and
- establishment of a safety and security cultures.

Technical Measures

Technical measures pose a physical barrier to a source, device or facility in order to separate it from unauthorised personnel and to deter, or to prevent, inadvertent or unauthorised access to, or removal of, a radioactive source.

Technical measures are generally hardware or security devices and include

- fences;
- walls;
- cages;
- transport packages;
- locks and interlocks for doors;
- locked shielded containers;
- intrusion-resistant source holding devices;
- access points with alarm.

Table 2 Summary of Security Measures

Specific Security Measures

<table>
<tr><th>Security Level
A Sources</th><th>Security Level
B Sources</th><th>Security Level
C Sources</th></tr>
<tr><td colspan="3">General administrative measures:</td></tr>
<tr><td>Daily accounting</td><td>Weekly accounting</td><td>Semi-annual accounting</td></tr>
<tr><td colspan="2">Access control to source location allowing timely detection of unauthorised access</td><td>Access control to source location</td></tr>
<tr><td colspan="3">Deterrence provided by:</td></tr>
<tr><td>Two technical measures separating the source from unauthorised personnel</td><td>Two measures (one technical) separating the source from unauthorised personnel</td><td>One technical measure separating the source from unauthorised personnel</td></tr>
<tr><td colspan="2">Specific emergency response plan</td><td>Generic emergency plan</td></tr>
<tr><td colspan="2">Background check</td><td rowspan="6"></td></tr>
<tr><td colspan="2">Security plan</td></tr>
<tr><td colspan="2">Information security</td></tr>
<tr><td colspan="2">Upgrade security for increased threat</td></tr>
<tr><td colspan="2">Timely Detection provided by:
Remotely monitored intruder alarm
Timely response to an alarm</td></tr>
<tr><td colspan="2">Local Alarm</td></tr>
</table>

FIFTEENTH SCHEDULE
(Regulation 124)

INDICATIVE LIST OF TYPES OF EXISTING EXPOSURE SITUATIONS

Exposure due to contamination of areas by residual radioactive material from:

(i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by these regulations;

(ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;

(iii) residues from past activities for which the undertaking is no longer legally accountable;

(a) Exposure to natural radiation sources, including:

(i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;

(ii) indoor external exposure from building materials;

(b) Exposure to commodities excluding food, animal feeding stuffs and drinking water incorporating

(i) radionuclides from contaminated areas specified in paragraph (a), or

(ii) naturally-occurring radionuclides.

SIXTEENTH SCHEDULE
(Regulation 64 and 127)

LIST OF ITEMS TO BE CONSIDERED IN PREPARING THE NATIONAL ACTION PLAN TO ADDRESS LONG-TERM RISKS FROM RADON EXPOSURES

1. Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and radium-226 content of rock or soil).

2. Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.

3. Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a safety assessment, considering for instance occupancy hours.

4. The basis for the establishment of reference levels for dwellings and workplaces. If applicable, the basis for the establishment of different reference levels for different uses of buildings (dwellings, buildings with public access, workplaces) as well as for existing and for new buildings.

5. Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.

6. Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under paragraph 2.

7. Strategies for facilitating post construction remedial action.

8. Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.

9. Schedules for reviews of the action plan.

10. Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking.

11. Guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.

12. Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.

13. Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non-smokers).

14. Where appropriate, consideration of other related issues and corresponding programmes such as programmes on energy saving and indoor air quality.

Amended by:
L.N. 184 of 2020.

SEVENTEENTH SCHEDULE
(Regulation 18 and 67)

SEVENTEENTH SCHEDULE
(Regulation 18 and 67)

QUALIFICATION AND EXPERIENCES FOR PERSONS INVOLVED IN MEDICAL EXPOSURES

1. Referrers shall have the following qualification and experience as detailed below

Practitioners shall have the following qualification and experience as detailed below:

Qualification	Registered medical doctors, or dentists, or Practitioners when additional exposures are clinically indicated
Experience	No initial experience needed

2. Practitioners qualification and experience

Practitioners shall have the following qualification and experience as detailed below:

Qualification	Medical doctors who are on the Specialist Registers held by the Medical Council for: Radiology; Radiotherapy; Nuclear Medicine,
	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.

3. Categorization of medical exposures

As the practical aspects of different procedures for medical exposures carry different levels of risk, both to the person performing the practical aspects and to the patient, the Commission has categorised medical exposures as shown in the below table using the graded approach. This categorisation is being done in relation to persons performing the practical aspects only

Risk Level	Type of medical exposure
High	Radiotherapy Brachytherapy Nuclear Medicine (diagnostic and therapeutic) Interventional Radiology Fluoroscopic Techniques CT Mammography
Medium	General Diagnostic Radiography Dental Radiography
Low	Low output Diagnostic Radiography (e.g. bone density)

4. Qualification and experience for persons performing the practical aspects

Persons performing the practical aspects shall have the following qualification and experience as detailed below:

(i) Persons performing the practical aspects of radiation producing medical equipment for medical purposes:

High Risk Procedures	Qualification	Practitioners with the proviso that a registered medical radiographer is in attendance during any form of intervention by medical doctors who are on the specialist registers listed in the table in part 1 of this Schedule. Other persons approved under regulation 69 as long as a practitioner is available
	Experience	First time registered medical radiographers shall have at least three months on the job orientation under the supervision of a registered medical radiographer approved to work in the specific area. Persons approved by under regulation 69 shall have three months on the job training under the supervision of a Practitioner

Medium Risk Procedures	Qualification	Practitioners, or Dentists for dental medical exposures Other persons approved under regulation 69
	Experience	First time registered medical radiographers, Practitioners, shall have at least one month on the job orientation under the supervision of an approved individual in the specific area. No initial experience for dental work performed by dental surgeons specific area. Persons approved by under regulation 69 shall have two months on the job training under the supervision of a Practitioner
Low Risk Procedures	Qualification	Practitioners, or Other persons approved under regulation 69
	Experience	No initial experience for practitioners Persons approved by under regulation 69 shall have two months on the job training under the supervision of a Practitioner.

(ii) Persons performing the practical aspects administering sealed or unsealed radioactive sources for medical exposure purposes:

Brachytherapy	Qualification	Registered on the specialist register for oncology and radiotherapy or Medical radiographer
	Experience	One month or several procedures of on the job orientation under the supervision of an approved individual in the specific area.
Therapeutic and Diagnostic Nuclear Medicine	Qualification	Registered on specialist register for nuclear medicine or registered medical doctor or registered medical radiographer , registered medical physicist as directed by an individual registered on specialist register for nuclear medicine
	Experience	One month or several procedures on the job orientation under the supervision of an approved individual in the specific area.

(iii) Persons performing the practical aspects of other aspects of medical exposures:

Gamma Camera/ Positron Emission Tomography	Qualification	Registered on specialist register for nuclear medicine or medical radiographer
	Experience	Three months on the job orientation under the supervision of registered individual on specialist register for nuclear medicine or medical radiographer.

(iv) Persons performing the practical aspects of radiation producing medical equipment for non medical purposes:

Quality Control Procedures	Qualification	Medical physicists registered with Council for the Professions Complementary to Medicine, Registered Medical radiographers, or persons specifically trained to carry out the quality control of the relevant equipment.
	Experience	At least nine months on the job orientation under the supervision of an approved QC individual or 300 hours of training in quality control.
Installation and Maintenance	Qualification	Persons specifically trained by the manufacturer in the areas that are needed to carry out their duty or trained by other engineers/technicians certified competent by the manufacturer
	Experience	One month on the job training under the supervision of an experienced installer

EIGHTEENTH SCHEDULE

(Regulation 74)

INFORMATION TO BE SUPPLIED TO THE SECRETARAIT EACH TIME AN ACCEPTANCE TEST IS PERFORMED:

(a) Full equipment details including

- type of equipment
- manufacturer
- model
- serial numbers
- year of manufacture
- year of Installation
- for x-ray equipment: Max KV. Max mA
- location of equipment

(b) Particulars of the test

- reason for performing test
- person(s) performing test
- date of test
- name of standard followed
- specified tolerances, manufactures specification and other reference documents if appropriate
- details of test equipment used, including calibration dates

(c) Previous tests

- Details of any on-site/factory tests performed by manufacturer and results of such tests

(d) For each of the required parameters tested the report should include:

- test procedure followed
- measured values
- manufacturers specification for that parameter.
- if no manufactures specification available, the reason why and the value the measured value was compared to
- statement if the equipment passes that parameter

NINETEENTH SCHEDULE
(Regulation 83(e))

EXPOSURE TO IONISING RADIATION TO AN EXTENT MUCH GREATER THAN INTENDED

If such an incident has or believed to have occurred, the undertaking has to carry out a preliminary investigation. Unless this investigation establishes that no such incident occurred, the Secretariat has to be immediately notified and a detailed investigation has to be carried out.

During the preliminary and, if applicable, during the detailed investigation, any process in connection with the incident, (from the receipt of the patient to the final reporting) shall be stopped from use until the investigation is carried out and any corrective actions taken. For example, these processes may include all the steps from patient receipt to the final reporting.

The table below shows the interpretation of the term "much greater than intended

Table 1

Medical exposure	Much Greater than intended multiplying factor applied to intended dose
Interventional radiology, radiographic and fluoroscopic procedures involving contrast agents, nuclear medicine with intended dose >5mSv and computed tomography examinations	1.5
Mammography, nuclear medicine with intended E≤5mSv but >0.5mSv, all other radiographic examinations not referred to elsewhere in this table.	10
Radiography of extremities, skull, dentition, shoulder, chest, elbow, knee and nuclear medicine with intended E≤ 0.5mSv	20

Beam therapy, brachytherapy	1.1 (whole course) or 1.2 (any fraction)
Unsealed radionuclide therapy	1.2 (any administration)

Procedural failures	
Incident	Undertaking's Duty
Incorrect diagnostic procedure	Preliminary investigation and inform the Secretariat
Wrong patient exposed to a dose of radiation	Preliminary investigation and inform the Secretariat
Reject exposures due to other parameters resulting in inadequate diagnostic information	Perform Reject Analyses and take corrective action. The reports, analyses and corrective actions to be documented and made available to the Secretariat

Any preliminary investigation reports shall be kept by the undertaking for a period of at least 2 years from the date it was made. If a detailed investigation is made, the report shall be kept for a period of at least 30 years from the date it was made.

TWENTIETH SCHEDULE
(Regulation 68(b))

REQUIREMENTS FORMEDICAL PHYSICS EXPERTS

Table 1
Undertaking's requirements for obtaining advice from Medical Physics Experts

<table>
<tr><th>Practice</th><th>Level of Involvement of the medical physics expert</th><th>Contractual agreement between undertaking and the medical physics expert</th></tr>
<tr><td>External Beam Radiotherapy</td><td rowspan="3">Close involvement:
To be present on site for at least part of the working day and to be available for consultation as required for any individual patient-specific issues</td><td rowspan="3">Documented agreement between undertaking and medical physics expert</td></tr>
<tr><td>Brachytherapy</td></tr>
<tr><td>Other Radiotherapeutic practices (Excluding standardized nuclear medicine practices)</td></tr>
<tr><td>Standardised nuclear medicine radiotherapeutic procedures</td><td rowspan="6">Shall be involved:
Monitor practices regularly and
be available for consultation as required and to respond for any individual patient-specific issues</td><td rowspan="6">Documented agreement between undertaking and medical physics expert</td></tr>
<tr><td>Diagnostic nuclear medicine procedures</td></tr>
<tr><td>Interventional Radiology</td></tr>
<tr><td>Computed Tomography</td></tr>
<tr><td>Other high dose radiodiagnostic practices</td></tr>
<tr><td>Health Screening</td></tr>
<tr><td>Other medical radiological practices not covered by above points</td><td>Involved as appropriate</td><td>None required</td></tr>
</table>

TWENTY-FIRST SCHEDULE
(Regulation 95(1)(a)

ELEMENTS OF NATIONAL RADIOACTIVITY MONITORING PROGRAMME

Table 1

	Sampling frequency
Ambient gamma dose rate	Continuous
Air particulates	Continuous
Coastal Waters	Quarterly
Soil	Annually
Water for human consumption	Monthly
Food	Monthly
Milk	Quarterly