THE PROTECTION FROM IONISING RADIATION AND NUCLEAR AND RADIOLOGICAL SAFETY AND SECURITY LAW OF 2018

Regulations according to section 62

The Protection from Ionising Radiation and Nuclear and Radiological Safety and Security (Laying down Basic Safety Standards for Protection against the Dangers arising from exposure to Ionising Radiation), Regulations of 2018

Regulation

SCHEDULES

Ninth Schedule:	Indicative list of types of building materials considered with regard to their emitted gamma radiation.
Tenth Schedule:	Definition and use of the activity concentration index for the gamma radiation emitted by building materials.
Eleventh Schedule:	Activity values defining high-activity sealed sources.
Twelfth Schedule:	Information to be provided in the records for high-activity sealed sources.
Thirteenth Schedule:	Requirements for undertakings responsible for a high-activity sealed source.
Fourteenth Schedule:	Identification and marking of high-activity sealed sources.

For the purposes of harmonization of the European Atomic Energy Community (Euratom) acts with title –

Official Journal of the E.U.: L13, 17.1.2014, p.1.

Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

L. 164(I)/2018

The Council of Ministers, exercising its powers under section 62 of the Protection from Ionising Radiation and Nuclear and Radiological Safety and Security Law of 2018, issues the following Regulations:

CHAPTER I – SCOPE AND APPLICATION

Short title.

1. These Regulations will be referred to as the Protection from Ionising Radiation and Nuclear and Radiological Safety and Security (Laying down Basic Safety Standards for Protection against the Dangers arising from exposure to Ionising Radiation), Regulations of 2018.

Interpretation.

2. (1) In these Regulations, unless the context otherwise implies –

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

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

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

"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;

“unsealed source” means a radioactive source in which the radioactive material is neither (a) permanently sealed in a capsule nor (b) closely bonded and in a solid form;

“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;

“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;

“Individual Radiological Monitoring Document” means a document issued by the Control Service for each outside worker based on Regulation 41, for the purpose of individual radiological monitoring of outside workers;

“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;

“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;

“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;

“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;

“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;

“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;

“practitioner” means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;

“medical radiological procedure” means any procedure giving rise to medical exposure;

“medical radiological installation” means a facility where medical radiological procedures are performed;

“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;

“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;

“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;

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"Law" means the Protection from Ionising Radiation and Nuclear and Radiological Safety and Security Law of 2018, as amended or replaced;

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

"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;

"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;

"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;

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

"standard values and relationships" mean values and relationships recommended in chapters 4 and 5 of International Commission on Radiological Protection (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 Control Service;

"medical physicist" means an individual who practices the profession of medical physicist or may provide medical physics services, is registered in the Medical Physicists Register of the Republic and holds a license to practice, according to the Registration of Medical Physicists Laws of 2008 and 2011, as amended or replaced;

L. 33(I)/2008
L. 45(I)/2011

"operator" means an individual who, in accordance with written instructions set by the undertaking or the employer, is authorised to carry out practical aspects of medical radiological procedures, and includes persons who carry out practical aspects of medical radiological procedures as part of their training, with the exception of cases operating under the direct supervision of a person who is adequately and appropriately educated and trained;

(2) All terms contained in these Regulations, unless otherwise stated in the text, have the meaning given to them in the Law.

Subject matter.

3. The Regulations establishes uniform 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.

Application.

4. –(1) These Regulations shall apply in all cases where the Law applies.

(2) These Regulations apply to self-employed persons as they apply to undertakings, employers and their employees, as if the self-employed person was both an employer and an employee.

CHAPTER II – SYSTEM OF RADIATION PROTECTION

Dose constraints for occupational, public, and medical exposure.

5. –(1) Dose constraints are established for the purpose of prospective optimisation of protection, as follows:

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(a) For occupational exposure, the undertaking or the employer, under the regulatory control of the Control Service, establishes dose constraints as an operational tool for optimisation, and notifies the Control Service as part of the authorisation procedure. In the case of outside workers, the dose constraints are established in cooperation between the employer and the undertaking, as set out in Regulation 41, and the Control Service is notified.

(b) For public exposure, the Control Service sets out the dose constraints for the individual dose that members of the public receive from the planned operation of an authorised practice. The Control Service ensures that the constraints are consistent with the dose limit for the sum of doses to the same individual from all authorised practices and radiation sources, which are considered important from a radiation protection point of view.

(c) For medical exposure, dose constraints apply only with regard to the protection of carers, comforters and volunteers participating in medical or biomedical research, as defined in Regulation 46.

(2) Dose constraints referred to in sub-regulation (1) are established in terms of individual effective or equivalent doses over a defined appropriate time period.

Reference levels.

6. –(1) The Control Service ensures that reference levels are established for emergency and existing exposure situations, as follows:

(a) For emergency exposure situations, reference levels are determined in accordance with the provisions of sections 53 and 54 of the Law.

(b) For existing exposure situations, reference levels are determined in accordance with the provisions of Regulation 62.

(2) Optimisation of protection shall give priority to exposures above the reference level and shall continue to be implemented below the reference level.

(3) −(a) The values chosen for reference levels shall depend upon the type of exposure situation. The choices of reference levels shall take into account both radiological protection requirements and societal criteria.

First Schedule.

(b) For public exposure the establishment of reference levels shall take into account the range of reference levels set out in First Schedule.

(c) For emergency occupational exposure, reference levels are determined in accordance with the provisions of Regulation 43.

(4) For existing exposure situations involving exposure to radon, the reference levels shall be set in terms of radon activity concentration in air as specified in Regulation 63 for members of the public and Regulation 44 for workers.

Age limit for exposed workers.

R.A.A. 77/2012
R.A.A. 43/2015

7. Subject to the provisions of the Safety and Health at Work (Youth Protection) Regulations of 2012 and 2015, as amended or replaced, and sub-regulation (2) of Regulation 10, persons under 18 years of age may not be assigned to any work which would result in them being exposed workers.

Dose limits for occupational exposure.

8. –(1) The undertaking or the employer ensures that, no employer who conducts or participates in a practice or activity with ionising radiation which includes or may include radiation exposure is exposed to radiation doses exceeding the dose limits set out in these Regulations.

(2) Dose limits for occupational exposure apply to the sum of the annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification to the Control Service in accordance with sub-regulation (3) of Regulation 44, and other occupational exposure from existing exposure situations in

accordance with section 57 of the Law. For emergency occupational exposure Regulation 43 is applied.

(3) The effective dose limit for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations, which have previously been approved by the Control Service, a higher effective dose of up to 50 mSv may be authorised by the Control Service, 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 20 mSv.

(4) In addition to the limits on effective dose laid down in sub-regulation (3) of these Regulations, the following limits on equivalent dose are applied:

(a) the equivalent dose limit for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any five consecutive years' subject to a maximum dose of 50 mSv in a single year.

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

(c) the equivalent dose limit for the extremities shall be 500 mSv per year.

Protection of pregnant and breastfeeding workers.

9. –(1) As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer of the pregnancy, the undertaking, and the employer ensure that the protection of the unborn child is comparable with that provided for members of the public, and in accordance with the provisions of the Protection of Maternity Law of 1997 to 2011, as amended or replaced.

L. 100(I)/1997
L. 45(I)/2001
L. 64(I)/2002
N. 109(I)/2007
L. 8(I)/2008
L. 43(I)/2008
L. 70(I)/2011

(2) In the cases referred to in sub-regulation (1) of this Regulation, any undertaking or employer ensures that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

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

Dose limits for apprentices and students.

10. −(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, are the same as the dose limits for occupational exposure laid down in Regulation 8.

R.A.A. 77/2012
R.A.A. 43/2015

(2) Subject to the provisions of the Safety and Health at Work (Youth Protection) Regulations of 2012 and 2015, as amended or replaced, 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 6 mSv per year.

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

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

(b) the limit on the equivalent dose for the skin shall be 150 mSv per year, 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 150 mSv per year.

(4) The dose limits for apprentices and students who are not subject to the provisions of sub-regulations (1), (2) and (3) of this Regulation are the same as the dose limits for members of the public as specified in Regulation 11.

Dose limits for public exposure.

11.–(1) The dose limits for public exposure are applied to the sum of annual exposures of a member of the public resulting from all authorised practices.

(2) The limit on the effective dose for public exposure is 1 mSv per year.

(3) In addition to the dose limit referred to in sub-regulation (2), the following limits on the equivalent dose are applied:

(a) the limit on the equivalent dose for the lens of the eye is 15 mSv per year;

(b) the limit on the equivalent dose for the skin is 50 mSv per year, averaged over any 1 cm^2 area of skin, regardless of the area exposed.

Estimation of the effective and equivalent dose.

12. (1) 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 the International Commission on Radiological Protection (ICRP) Publication 116 shall be used.

(2) The Control Service may approve the use of special methods in specific cases relating to the physicochemical properties of the radionuclide or other characteristics of the exposure condition or the exposed individual.

CHAPTER III − REQUIREMENTS FOR RADIATION PROTECTION EDUCATION, TRAINING AND INFORMATION

Training of exposed workers and information provided to them.

13.–(1) The undertaking or, in the case of an outside worker, the employer, informs the 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, their employer shall ensure that the information required in paragraphs (a), (b) and (e) of this sub-regulation is provided.

(2) The undertaking or, in case of outside workers, the employer, informs the 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, informs 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, 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 or employer responsible for high-activity sealed sources shall ensure that such training includes specific requirements for the safe 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.

14.–(1) The management of installations where orphan sources are most likely to be found or processed, including large metal scrap yards and major metal scrap recycling installations, and in significant nodal transit points, is informed of the possibility that they may be confronted with a source.

(2) The management of installations referred to in sub-regulation (1) to ensures that where workers in their installation may be confronted with a source, they 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 in the case of exposure;

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

Prior information and training for emergency workers.

15.–(1) Emergency workers who are identified in an emergency response plan or management system are given adequate and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies and the type of intervention.

(2) In the case of an emergency, the information referred to in sub-regulation (1) shall be supplemented appropriately, having regard to the specific circumstances.

(3) The undertaking or the organisation responsible for the protection of emergency workers provides to emergency workers referred to in sub-regulation (1) appropriate training as provided for in the emergency

management system set out in section 53 of the Law. Where appropriate, this training shall include practical exercises.

(4) In addition to the emergency response training referred to in sub-regulation (3), the undertaking or the organisation responsible for the protection of emergency workers provides these workers with appropriate radiation protection training and information.

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

16. –(1) The undertaking or the employer ensures that practitioners and the individuals involved in the practical aspects of medical radiological procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.

(2) The competent authority ensures that appropriate curricula are established and recognises the corresponding diplomas, certificates or formal qualifications of the workers in radiation protection issues.

(3) The undertaking or the employer ensures that only individuals recognised by the Control Service may participate in practical aspects of medical radiological procedures as set out in sub-regulation (2) of Regulation 47.

(4) The competent authority, in cooperation, where appropriate, with the involved scientific, educational and professional bodies or organisations, ensures that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, training is provided on these techniques and the relevant radiation protection requirements.

(5) The competent authority, in cooperation, where appropriate, with the involved scientific, educational and professional bodies or organisations, encourages the introduction of courses on radiation protection in the basic curriculum of medical and dental schools operating in the Republic.

CHAPTER IV − JUSTIFICATION AND PROHIBITION OF PRACTICES

Justification of practices.

17.–(1) The undertaking or the employer ensures that all new classes or types of practices resulting in exposure to ionising radiation are justified before being adopted, according with sub-regulations (2), (3) and (4) of this Regulation.

(2) For the purpose of sub-regulation (1) of this Regulation:

(a) All new categories or new types of practical medical and non-medical exposures are justified by the Control Service before they are adopted.

(b) Existing classes or types of practices are reviewed 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.

(3) Practices involving occupational and public exposures shall be justified as a class or type of practice, taking into account both categories of occupational exposure and public exposure.

(4) Practices involving medical exposure shall be justified both as a class or type of practice, taking into account medical and, where relevant, associated occupational and public exposures, and at the level of each individual medical exposure as specified in Regulation 45.

Practices involving consumer products.

18.–(1) Any undertaking intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, shall provide the Control Service with all relevant information, including that listed in Part I of the Second Schedule, so as to allow the implementation of the justification requirement in sub-regulation (1) of the Regulation 17.

Second Schedule Part I

(2) On the basis of an assessment of this information, the Control Service, as outlined in Part II of Second Schedule, decides whether the intended use of the consumer product is justified.

Second Schedule Part II

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

(4) The sale or the making available to the public of consumer products is prohibited if their intended use is not justified or their use would not fulfil the criteria for exemption from notification under section 16 of the Law.

Prohibition of practices.

Official Journal of the E.U.: L66, 13.3.1999

19. –(1) Without prejudice to the Directive 1999/2/EC, 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 competent authority may evaluate specific types of practices within this class with regard to their justification.

(2) Subject to the provisions of section 11(2) of the Law, 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, are prohibited. The import or export of such products or materials is also prohibited.

Practices involving the deliberate exposure of humans for non-medical imaging purposes.

20.–(1) Practices involving non-medical imaging exposure are shown in the Third Schedule.

Third Schedule

(2) Special attention is given to the justification of practices involving non-medical imaging exposure, in particular:

(a) all types of practices involving non-medical imaging exposure shall be justified before being generally accepted;

(b) each particular application of a generally accepted type of practice shall be justified;

(c) all individual non-medical imaging exposure procedures using medical radiological equipment shall be justified in advance, taking into account the specific objectives of the procedure and the characteristics of the individual involved;

(d) the general and particular justification of practices involving non-medical imaging exposure, as specified in (a) and (b) of this sub-regulation, may be subject to review by the Control Service;

(e) circumstances warranting non-medical imaging exposures, without individual justification of each exposure, shall be subject to regular review.

(3) The Control Service may exempt justified practices involving non-medical imaging exposure using medical radiological equipment from the requirement for dose constraints according to paragraph (b) of sub-regulation (1) of the Regulation 5 and from the dose limits set out in Regulation 11.

(4) The following applies to practices involving non-medical imaging exposure:

(a) the practice is subject to authorisation by the Control Service;

(b) requirements for the practice, including criteria for individual implementation, are established by the Control Service, in cooperation with other relevant bodies and medical scientific societies, as appropriate;

(c) for procedures using medical radiological equipment:

(i) relevant requirements identified for medical exposure as set out in Chapter VI 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, recognised by the Control Service, 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;

(d) for procedures not using medical radiological equipment, dose constraints are significantly below the dose limit for members of the public and do not exceed 0.5 mSv per type of practice per year, provided that the non-medical exposure is applied to individuals for whom the necessity of this exposure has been justified in advance;

(e) non-medical exposures without personalized justification are prohibited, unless there are reasons for national security, which have been assessed as such by the Control Service during the authorisation of that practice. In this case, the dose constraints are set by the competent authority in the context of the authorisation of this type of practice and do not exceed 0.1 mSv per type of practice per year;

(f) information is provided by the practitioner and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities of the Republic may proceed, in some exceptional cases, to a non-medical imaging exposure without consent of the individual according to national legislation and practice, where they exist.

CHAPTER V – OCCUPATIONAL EXPOSURE

Responsibilities and obligations regarding occupational exposure.

21. –(1) The undertaking or the employer is responsible for assessing and implementing arrangements for the radiation protection of exposed workers. The management of the undertaking or employer takes measures to cultivate and maintain in the personnel safety and security culture, which includes individual and collective commitment to safety and security. The undertaking or, in the case of outside workers, the employer:

(a) prepares and implements measures for the radiation protection of exposed workers;

(b) prepares and implements safety and security programs for ionising radiation that are appropriate for each exposure condition. Programs include setting safety and security targets, as well as implementing appropriate and adequate measures, depending on the radiation hazards associated with each exposure situation;

(c) systematically reviews the programs referred to in paragraph (b) of this sub-regulation for their effectiveness, identifies any faults or deficiencies and takes measures to prevent conditions that may lead to their re-creation;

(d) ensures that the measures taken are capable of achieving the goals set.

(2) In the case of outside workers, the responsibilities of the undertaking and the employer of outside workers are stipulated in Regulation 41.

(3) Without prejudice to sub-regulations (1) and (2) of this Regulation, the undertaking or, in case of outside workers, the employer, or any other body or organisation employing individuals arranges for a clear allocation of responsibilities for the protection of workers in any exposure situation, 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 sub-regulation (3) of Regulation 44.

Provided that, the above also apply to the protection of self-employed individuals and individuals who work on a voluntary basis.

(4) Employers have access to information on the possible exposure of their employees under the responsibility of another employer or undertaking.

Operational protection of exposed workers.

22. The undertaking or the employer ensures that the operational protection of exposed workers is based, in accordance with the relevant provisions of these Regulation, on:

(a) prior evaluation to identify the nature and magnitude of the radiological risk to exposed workers;

(b) optimisation of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures;

(c) classification of exposed workers into different categories;

(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.

23. The undertaking or the employer ensures that:

(a) The exposure conditions and operational protection of apprentices and students aged 18 years or over referred to in sub-regulation (1) of Regulation 10 is equivalent to that of exposed workers of category A or B as appropriate.

(b) The exposure conditions and operational protection of apprentices and students aged between 16 and 18 years referred to in sub-regulation (2) of the Regulation 10 is equivalent to that of exposed workers of category B.

Consultation with a radiation protection expert.

24. Based on the provisions of article (15) of section 45 of the Law, each undertaking or employer, depending on the practice and based on the graded approach, seeks advice from radiation protection experts within their areas of competence as outlined in Regulation 68, 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 checks of the effectiveness of protective devices and techniques;

(e) regular calibration of measuring instruments and regular checks that they are serviceable and correctly used.

Arrangements in workplaces.

25. –(1) The undertaking or the employer ensures that for the purposes of radiation protection, arrangements are made as regards all workplaces where workers are liable to receive an exposure greater than an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities.

Such arrangements shall be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.

(2) (a) For workplaces specified in sub-regulation (3) of Regulation 44, and where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value determined by the Control Service, these shall be managed as a planned exposure situation and the Control Service determines which requirements set out in this Chapter are appropriate.

(b) For workplaces specified in sub-regulation (3) of Regulation 44, and where the effective dose to workers is less than or equal to 6 mSv per year or the exposure less than the corresponding time-integrated radon exposure value that may be determined by the Control Service, the undertaking or the employer applies and follows appropriate procedures so that workers' exposures are kept under review.

(3) The undertaking or the employer operating aircraft where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, apply the relevant requirements set out in this Chapter, allowing for the specific features of this exposure situation. Where the effective dose to the crew is liable to be above 1 mSv per year, the undertaking or the employer take appropriate measures, in particular:

(a) to assess the exposure of the crew concerned and send the results to the Control Service;

(b) to take into account the assessed exposure when organising working schedules with a view to reducing the doses of highly exposed crew and, where possible, the exposure should not exceed 6 mSv of effective dose per year;

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

(d) to apply sub-regulation (1) of Regulation 9 to pregnant air crew.

Classification of workplaces.

26. –(1) The undertaking or the employer implements measures in workplaces that include a classification into different areas, where appropriate, on the basis of an assessment of the expected annual doses and the probability and magnitude of potential exposures.

(2) The undertaking or the employer makes a distinction between controlled areas and supervised areas. The Control Service may establish guidance on the classification of controlled and supervised areas with regard to particular circumstances.

(3) The undertaking or the employer keeps under review the working conditions in controlled and supervised areas.

Controlled areas.

27. –(1) Based on the provisions of Regulation 26, the minimum requirements for a controlled areas are:

(a) the controlled areas are delineated and access to them is restricted to individuals who have received appropriate instructions and shall be controlled in accordance with written procedures provided by the undertaking or the employer. 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 areas, radiological surveillance of the workplace is organised in accordance with the provisions of Regulation 29;

(c) signs indicating the type of areas, the nature of the sources and their inherent risks is displayed;

(d) working instructions appropriate to the radiological risk associated with the sources and the operations involved are laid down.

(e) the workers receive specific training in connection with the characteristics of the workplace and the activities;

(f) the workers are provided with the appropriate personal protective equipment.

(2) The undertaking or the employer is responsible for the implementation of these duties based on the provisions of sub-regulation (1) of this Regulation taking into account the advice provided by the radiation protection expert.

Supervised areas.

28. –(1) Based on the provisions of Regulation 26, the minimum requirements for a supervised areas are the following:

(a) taking into account the nature and extent of radiological risks in the supervised area, radiological surveillance of the workplace is organised in accordance with the provisions of Regulation 29;

(b) taking into account each specific case, signs indicating the type of area, the nature of the sources and their inherent risks is displayed;

(c) taking into account each specific case, working instructions appropriate to the radiological risk associated with the sources and the operations involved are laid down.

(2) The undertaking or the employer is responsible for the implementation of these duties based on the provisions of sub-regulation (1) of this Regulation taking into account the advice provided by the radiation protection expert.

Radiological surveillance of the workplace.

29. –(1) The radiological surveillance of the workplace referred to in paragraph (b) of sub-regulation (1) of Regulation 27 and paragraph (a) of sub-regulation (1) of Regulation 28 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) The results of these measurements are recorded and used, if necessary, for estimating individual doses, as provided for in Regulation 31.

Categorisation of exposed workers.

30. –(1) For the purposes of monitoring and surveillance, a distinction is made between two categories of exposed workers:

(a) Category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv 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, decide on the categorisation of individual workers prior to them 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.

31. –(1) (a) The undertaking or the employer is obliged to systematically monitor category A workers based on individual measurements performed by dosimetry services recognised by the Control Service.

(b) In cases where category A workers are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, the undertaking or, in the case of outside workers, the employer, an adequate system for monitoring is set up.

(2) (a) The monitoring for category B workers is at least sufficient to demonstrate that such workers are correctly classified in category B.

(b) The Control Service may require individual monitoring and, if necessary, the undertaking or, in the case of outside workers, the employer, individual measurements, performed by a dosimetry service, for category B workers.

(3) In cases where individual measurements are not possible or inadequate, the individual monitoring is 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 29 or on the basis of calculation methods approved by the Control Service.

Dose assessment in the case of accidental exposure.

32. In the case of accidental exposure, the undertaking or, in the case of outside workers, the employer, assess the relevant doses and their distribution in the workers' body.

Recording and reporting of results of individual monitoring and records keeping.

33. –(1) The undertaking or, in the case of outside workers, the employer, ensures that a record containing the results of individual monitoring is kept for each category A worker and for each category B worker where such monitoring is required.

(2) For the purposes of sub-regulation (1), the following information on exposed workers is retained by the undertaking or, in the case of outside workers, the employer:

(a) a record of the exposures measured or estimated, as appropriate, of individual doses pursuant to Regulations 31, 32, 41, 42, 43;

(b) in the case of exposures as referred to in Regulations 32, 42 and 43, 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) of this Regulation is 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 32, 42 and 43 are recorded separately in the dose record referred to in sub-regulation (1) of this Regulation.

(5) The dose record referred to in sub-regulation (1) of this Regulation is submitted to the data system for individual radiological monitoring established by the Control Service in accordance with the provisions of Fourth Schedule.

Fourth Schedule

Access to the results of individual monitoring.

34. –(1) The results of the individual monitoring set out in Regulation 31, 32, 42, 43:

(a) made available to the Control Service, to the undertaking, and to the employer of outside workers;

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

(c) submitted to the occupational health service in order for it to interpret the implications of the results for human health, as provided for in sub-regulation (2) of Regulation 35;

(d) submitted to the data system for individual radiological monitoring established by the Control Service in accordance with provisions set out in Fourth Schedule.

Fourth Schedule

(2) The undertaking, or in case of outside workers, the employer, grants 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) The Control Service may determine the arrangements under which the results of individual monitoring are conveyed.

Fourth Schedule Part II

(4) The data system for individual radiological monitoring shall cover at least the data listed in Fourth Schedule, Part II.

(5) In the case of an accidental exposure, the undertaking or, in the case of outside workers, the employer, communicates the results of individual monitoring and dose assessments to the individual and the Control Service without delay.

(6) The undertaking or, in the case of outside workers, the employer, ensures that arrangements are in place for the appropriate exchange of all relevant information on the doses previously received by a worker, among the undertaking, in the case of an outside worker, the employer, the Control Service, occupational health services, radiation protection experts, or dosimetry services, in order:

(a) to perform the medical examination prior to employment or classification as a category A worker pursuant to Regulation 35; and

(b) to control the further exposure of workers.

Provided that, any undertaking or employer conducts a practice or activity with ionising radiation, which may involve radiation exposure of other employer workers, these employers and the undertaking shall cooperate and exchange the information referred to in this Regulation, to the extent necessary to protect their workers and comply with the provisions of these Regulations.

Medical surveillance of exposed workers.

35. –(1) The medical surveillance of exposed workers is based on the principles that govern occupational medicine generally.

(2) The medical surveillance of category A workers is undertaken by the occupational health service. This medical surveillance allows 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 has access to any relevant information they require, including the environmental conditions in the working premises of the exposed workers.

(3) Medical surveillance includes:

(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;

(β) 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 the occupational health service considers necessary, is depended on the type of work and on the individual worker's state of health.

(4) The 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.

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(5) The provisions of this Regulation for the medical surveillance of the workers, as well as the relevant provisions of the Regulations of this Chapter are applied in accordance with the provisions of the Safety and Health at Work (Health Surveillance) Regulations of 2017, as amended or replaced.

Medical classification.

36. Each occupational health service applies the following medical classification is established with respect to fitness for work as a category A worker:

(a) fit;

(b) fit, subject to certain conditions;

(c) unfit.

Prohibition to employ or classify unfit workers.

37. The undertaking or the employer ensures that no worker is 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.

38. –(1) (a) The undertaking or, in the case of outside workers, the employer, ensures that a medical record is opened for each category A worker and kept up to date so long as the worker remains a worker in that category.

(b) The medical record is kept by the undertaking or, in the case of outside workers, the employer and 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 33.

Special medical surveillance.

39. –(1) In addition to the medical surveillance of exposed workers provided for in Regulation 35, provision is made for any further action considered necessary by the 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 8 has been exceeded.

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

Appeals.

40. The undertaking or, in the case of outside workers, the employer, may, in case of disagreement, submit an objection to the occupational health service against the findings and decisions made pursuant to Regulations 36,

37 and 39 with which he disagrees, requesting the revision of the finding and decision and, in case he disagrees with the new finding or decision, to submit an objection to the Control Service.

Provided that, until the examination of the objection and the issuance of a relevant decision by the Control Service, findings and decisions made pursuant to Regulations 36, 37 and 39 shall apply.

Protection of outside workers.

41. –(1) The system for individual radiological monitoring affords outside workers equivalent protection to that for exposed workers employed on a permanent basis by the undertaking. For this purpose, the employer of the outside workers ensures that:

(a) any outside worker whom he employs and is classified as Category A is provided with an appropriate Individual Radiological Monitoring Document, in accordance with the Fifth Schedule, Part I which is prohibited to be transferred to any other exposed worker and in which all relevant information is recorded; and

Fifth Schedule
Part I

(b) the information recorded in the Individual Radiological Monitoring Document of any of its employees, as set out in paragraph (a), is updated at all times during the entire period of employment of the outside worker.

The Individual Radiological Monitoring Document is issued by the Control Service and has a unique identification number.

(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, the undertaking shall:

(a) for category A outside workers entering controlled areas, check that the outside worker concerned has been classed 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 sub-regulation (1) of Regulation 13;

(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 sub-regulation (1) of Regulation 28;

(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 radiation protection as defined in Chapter II of these Regulations;

(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 Fifth Schedule, Part III.

Fifth Schedule
Part III

(4) The employer of outside workers ensures, 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, and that the undertaking:

(a) ensures compliance with the system of radiation protection as defined in Chapter II of these Regulations;

(b) ensures that the information and training in the field of radiation protection referred to in paragraphs (a), (b) and (e) of sub-regulation (1) and sub-regulations (2), (3) and (4) of Regulation 13;

(c) guarantees that their workers are subject to appropriate assessment of exposure and, for category A workers, medical surveillance, under the conditions laid down in Regulations 29 and 31 to 39;

(d) ensures that the radiological data from the individual exposure monitoring of each of their category A workers within the meaning of Fifth Schedule, Part II are sent to the Control Service and kept up to date in the data system for individual radiological monitoring referred to in paragraph(d) of sub-regulation (1) of Regulation 34.

Fifth Schedule Part II

(5) Without prejudice to the responsibilities of the undertaking or employer, all outside workers make their own contributions, as far as practicable, towards the protection to be afforded to them by the radiological monitoring system referred to in sub-regulation (1) of this Regulation.

Specially authorised exposures.

42. –(1) In exceptional circumstances evaluated case by case, excluding emergencies, the Control Service may, upon application from the undertaking or the employer and if deemed necessary for conducting specific operations, authorise individual occupational exposures of identified workers exceeding the dose limits set out in Regulation 8, 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 Control Service.

(2) In the cases where the provisions of sub-regulation (1) of this Regulation apply, the following terms shall be taken into account:

(a) only category A workers as defined in Regulations 30 or spacecraft crew 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 discusses them with the workers, their representatives, the 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 records referred to in Regulation 38 and the individual record referred to in Regulation 33.

(3) Exceeding of dose limits as a result of specially authorised exposures does not necessarily constitute a reason for excluding workers from their usual occupation or transferring them, without their agreement.

(4) The exposure of spacecraft crew above the dose limits is managed as a specially authorised exposure.

Emergency occupational exposure.

43. –(1) Emergency occupational exposures remain, whenever possible, below the values of the dose limits laid down in Regulation 8.

(2) For situations where the condition referred in sub-regulation (1) is not feasible, the following conditions are applied:

(a) reference levels for emergency occupational exposure shall be set, in general below an effective dose of 100 mSv and apply both to the national emergency response plan and to the internal emergency response plans of the undertakings;

(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 is set above 100 mSv, but not exceeding 500 mSv.

(3) Emergency workers who are liable to undertake actions whereby an effective dose of 100 mSv may be exceeded are clearly and comprehensively informed in advance of the associated health risks and the available protection measures and undertake these actions voluntarily.

Workers who know they are pregnant or may be pregnant are exempt from the above actions.

(4) In the event of an emergency occupational exposure, the undertaking or, where applicable, the emergency response body or agency, shall ensure the required radiological monitoring of emergency workers. 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, the undertaking or, where applicable, the emergency response body or agency, shall require special medical surveillance of emergency workers, as defined in Regulation 39, to be carried out as appropriate to the circumstances.

Radon in workplaces.

44. –(1) The national reference levels for the annual average activity concentration of indoor radon in workplaces is 300 Bq m^{-3}.

(2) For the following workplaces, the undertaking or employer ensures that radon measurements are carried out:

(a) in workplaces within the areas identified in accordance with section 60 of the Law, that are located on the ground floor or basement level, taking into account parameters contained in the national action plan as under the same section of the Law, as well as

(b) in specific types of workplaces identified in the national action plan.

(3) In areas within workplaces, where the radon concentration, as an annual average, continues to exceed the national reference level of sub-regulation (1), despite the actions taken in accordance with the principle of optimisation as set out in Chapter II of these Regulations, the undertaking or the employer notifies the Control Service for this situation, in accordance with the graded approach and the provisions of section 13 of the Law, and the sub-regulation (2) of Regulation 25 is also applied.

CHAPTER VI – MEDICAL EXPOSURES

Justification.

45. –(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) The principle defined in sub-regulation (1) of this Regulation is applied in the following ways:

(a) The Control Service justifies new types of practices involving medical exposure in advance before being generally adopted;

(b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved;

(c) if a type of practice involving medical exposure is not justified in general, a specific individual exposure of this type can be justified, where appropriate, in special circumstances, to be evaluated on a case-by-case basis and documented;

(d) the referrer and the practitioner seek to obtain previous diagnostic information or medical records relevant to the planned exposure and consider this data to avoid unnecessary exposure;

(e) medical exposures for medical or biomedical research are justified in advanced and authorised by the competent authority. In its decision, the competent authority takes into account, where appropriate, the opinion of the Cyprus National Bioethics Committee;

(f) specific justification for medical radiological procedures to be performed as part of a health screening programme are carried out by the Control Service in conjunction with appropriate medical scientific societies or relevant bodies;

(g) the exposure of carers and comforters show a sufficient net benefit, taking into account the direct health benefits to a patient, the possible benefits to the carers and comforters and the detriment that the exposure might cause;

(h) any medical radiological procedure on an asymptomatic individual, to be performed for the early detection of disease, is performed as part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and the Control Service. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by paragraph (d) of sub-regulation (1) of Regulation 47.

Optimisation.

46. –(1) The undertaking or employer ensures that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

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.

(2) The Control Service may establish and regularly review, where required, diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

Provided that, these levels should not be systematically exceeded during standard procedures, if good practice is applied in terms of diagnosis and technical performance of the equipment.

(3) 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 set at 1 mSv per year. This limit can be increased to 5 mSv per 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 5 mSv.

(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.

(4) 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.

(5) For carers and comforters dose constraints are determined as follows:

(a) the dose constraint for the duration of care of a particular patient is set at 5 mSv;

(b) the annual dose constraint in case of care of more than one patient and for a duration exceeding one year is set at 15 mSv;

(c) the dose constraint in case of care of a particular patient, in the case that the care is provided by pregnant carers, includes the cumulative dose that the unborn child may receive and is set at 1 mSv throughout pregnancy;

(d) the following dose constraints in case of care of people in the family or close patients undergoing treatment with I-131 apply:

(i) Minors (including unborn child): 1 mSv
(ii) Adults up to 60 years of age: 3 mSv
(iii) Adults over 60 years of age: 15 mSv

(e) the above dose constraints may be revised by the Control Service.

(f) the undertaking or employer determines appropriate guidelines for the exposure of carers and comforters and ensures that the doses to which carers and comforters are exposed to are recorded in an appropriate registry. This information shall be submitted or sent to the Control Service when requested.

(6) In the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, provides the patient or his

representative, in a way that is understandable in language for the patient or his representative, with:

(i) information on the risks of ionising radiation; and

(ii) appropriate written and oral instructions, with a view to restricting doses to persons in contact with the patient, as far as reasonably achievable, that shall be handed out before leaving the hospital or clinic or a similar institution.

Responsibilities and obligations regarding medical exposures.

47. –(1) During medical exposure the following applies:

(a) any medical exposure takes place under the clinical responsibility of a practitioner;

(b) the practitioner, the medical physics expert, the medical physicist, the radiation protection officer and those entitled to carry out practical aspects during medical exposure are involved in the optimisation process;

(c) the referrer and the practitioner are involved in the justification process of individual medical exposures;

(d) wherever practicable and prior to the exposure taking place, the practitioner or the referrer ensures 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 (f) of sub-regulation (5) of Regulation 46.

(2) Practical aspects of medical radiological procedures may be delegated by the undertaking or the employer or the practitioner, as appropriate, to one or more individuals entitled to act in this respect in a recognised field of specialisation.

Observance of procedures.

48. The undertaking or the employer ensures that:

(a) there are written instructions in a way that is understandable in language for the personnel involved in medical exposure, including the requirements referred to in Sixth Schedule, and

Sixth Schedule

(i) take all appropriate and adequate measures so that these instructions are followed by practitioners or operators, or

(ii) when the employer is both a practitioner and an operator he shall follow these instructions himself.

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

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

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

(e) in medical radiological practices, a medical physics expert is appropriately involved, and may be assisted by medical physicists, and the level of his involvement is commensurate with the radiological risk posed by the practice. In particular:

(i) in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved;

(ii) in standardised therapeutical nuclear medicine practices as well as in radiodiagnostic and interventional radiology practices, involving high doses as referred to in paragraph (c) of sub-regulation (1) of Regulation 51, a medical physics expert shall be involved;

(iii) for other medical radiological practices not covered by paragraph (i) and (ii), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure.

(f) clinical audits are carried out in accordance with national procedures;

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

Training and recognition.

49. –(1) No practitioner or operator can perform medical exposures or carry out any practical aspect without having appropriate theoretical and practical training in radiological techniques, as well as appropriate professional qualifications in the field of radiation protection.

Seventh Schedule

Practitioner or operator with appropriate education or training means a practitioner or operator who meets at least the requirements set out in Seventh Schedule.

(2) The undertaking or operator prepares and maintains for each radiological facility an appropriate registry with data for all the practitioners, operators or medical physics experts and in the case that the employer is at the same time a practitioner and operator, a registry with data on his own training, that shows the time periods during which the above persons received appropriate and adequate education or training as well as the nature of that education or training.

(3) The registry referred to in sub-regulation (2) of this Regulation shall be updated at all times and submitted or sent by the undertaking to the Control Service when requested.

(4) The undertaking or the employer ensures that training and recognition requirements, as laid down in sections 47 and 48 of the Law and Regulation 16, are met for the practitioner, the medical physics expert, the medical physicist, the radiation protection officers and the individuals referred to in sub-regulation (2) of Regulation 47.

Technical equipment and patient doses recording.

50. –(1) The undertaking ensures that:

(a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;

(b) an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the Control Service;

(c) appropriate quality assurance programmes and assessment of dose or verification of administered activity are implemented; and

(d) acceptance testing is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any maintenance procedure liable to affect the performance.

(2) The undertaking takes necessary measures to improve inadequate or defective performance of medical radiological equipment in use.

(3) The Control Service may adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.

(4) In accordance with the provisions of these Regulations the undertaking ensures that:

(a) the use of fluoroscopy equipment without a system 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 the entry into force of these Regulations and grants an authorisation is 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 the entry into force of these Regulations that has an authorisation is 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 paragraph (d) of sub-regulation (4) of this Regulation to the record of the examination. Equipment installed prior to the entry into force of these Regulations that has an authorisation is exempted from this requirement.

(f) without prejudice to paragraphs (c), (d) and (e) of sub-regulation (3) of this Regulation, 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.

(5) The undertaking ensures that patient doses are either recorded automatically by medical radiological equipment producing ionising radiation or are produced by calculation or estimation and are kept in a registry.

Special practices.

51. –(1) The undertaking ensures that appropriate medical radiological equipment, practical techniques and ancillary equipment are 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.

Provided that, special attention shall be given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices.

(2) Practitioners and those individuals referred to in sub-regulation (2) of Regulation 47 who perform the exposures referred to in sub-regulation (1) of this Regulation obtain appropriate training on these medical radiological practices as required by Regulation 16.

Special protection during pregnancy and breastfeeding.

52. –(1) The undertaking ensures that the referrer or the practitioner, as appropriate, inquires 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-regulation (1), (2) and (3) of this Regulation, the undertaking takes measures to increase the awareness of individuals to whom this Regulations applies, through measures such as public notices in appropriate places.

Accidental and unintended exposures.

53. The undertaking ensures 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 the undertaking implements an 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)

(i) he declares as soon as possible to the Control Service the occurrence of significant events as defined by the competent authority;

(ii) the results of the investigation and the corrective measures to avoid such events are reported to the Control Service within the time period specified by the Control Service;

(f) 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.

54.−(1) The Control Service estimates the distribution of individual doses from medical exposure for radiodiagnostic and interventional radiology, taking into consideration where appropriate the distribution by age and gender of the exposed.

(2) For the purpose referred to in sub-regulation (1), any undertaking that conducts a medical exposure practice sends to the Control Service, on an

annual basis, the required information, in a form specified by the Control Service, for the above estimation.

CHAPTER VII − PUBLIC EXPOSURES

Operational protection of members of the public.

55. –(1) The operational protection of members of the public in normal circumstances from practices subject to licensing includes the following:

(a) examination and approval by the Control Service 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) acceptance into service by the Control Service of the facility subject to 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) examination and approval by the Control Service of plans for the discharge of radioactive effluents;

(d) measures by the undertaking to control the access of members of the public to the facility.

(2) The Control Service, where appropriate, establishes authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which:

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

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

In addition, these discharge authorisations shall take into account, where appropriate, the results of a generic screening assessment based on internationally recognised scientific guidance, where such an assessment

has been required to demonstrate that environmental criteria for long-term human health protection are met.

(3) The protection of members of the public in normal circumstances and from practices subject to authorisation through registration is regulated by the Law.

Estimation of doses to the members of the public.

56. –(1) The competent authority ensures that all necessary measures are taken, as applicable, so that the contribution of each practice to the public exposure as a whole is kept as low as reasonably achievable, taking into account economic and social factors, and that all of these contributions are regularly evaluated.

(2) The undertaking or employer ensures that arrangements are made for the estimation of doses to members of the public from authorised practices. The extent of such arrangements shall be proportionate to the exposure risk involved.

(3) The Control Service identifies the practices for which an assessment of doses to members of the public shall be carried out. The competent authority specifies those practices for which this assessment needs to be carried out in a realistic way and those for which an assessment is sufficient.

(4) For the assessment of doses to the members of the public, the Control Service:

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

(c) ensures that the undertaking or the employer estimates of doses to the representative person including:

(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) of this Regulation, is liable to receive;

(d) requires records to be kept and be made available on request to all stakeholders 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.

Monitoring of radioactive discharges.

57.–(1) The undertaking responsible for practices where a discharge authorisation is granted, is required to monitor appropriately or where appropriate evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results to the Control Service.

(2) Any undertaking responsible for a nuclear power reactor or reprocessing plant is required to monitor radioactive discharges and report them to the Control Service.

Tasks for the undertaking or employer.

58. The undertaking or the employer shall:

(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) of this Regulation and ensure the regular calibration 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) of this Regulation.

Emergency response.

59. –(1) The undertaking or the employer notifies the Control Service immediately of any emergency in relation to the practices for which it is responsible and takes all appropriate actions to reduce the consequences.

(2) In the event of an emergency on the territory of the Republic, the undertaking or the employer concerned makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.

(3) The undertaking or the employer, through the internal emergency response plan and, as appropriate, emergency response bodies or agencies who participate in the national emergency response plan ensure that provision is made for protective measures with regard to:

(a) the radiation source, to reduce or stop the irradiation, 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.

(4) In the event of an emergency in or outside the territory of the Republic, the competent authority draws up an emergency response plan or plans, as set out in section 54 of the Law, whereby the elements included in are indicated in the Schedule referred to in article (2) of this section, and, among others, require:

(a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan;

(b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

(5) The competent authority ensures, if the situations so require, including through the national emergency response plan or plans, that the competent services of the state make provision to organise the medical treatment of those affected from radiation exposure due to emergency situations.

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

60. –(1) The undertaking ensures 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) Without prejudice to sub-regulation (1) of this Regulation, in case of emergency exposure situations, the Control Service, in collaboration with other agencies or organizations when needed, ensures that members of the public who may be harmed are informed of the health protection measures applied in their case and of the actions they shall take in such cases.

Eighth Schedule Part I

(3) The information supplied referred to in sub-regulations (1) and (2) of this Regulation include at least the elements set out in Part I of Eight Schedule.

(4) The information supplied referred to in sub-regulation (3) of this Regulation is communicated to the members of the public referred to in sub-regulation (1) of this Regulation without any request being made.

(5) The undertaking updates the information provided by this Regulation and distributes it at regular intervals and whenever significant changes take place. This information is continuously available to the public.

Informing members of the public who are actually affected in an emergency.

61.–(1) When an emergency occurs, the undertaking informs without delay the Control Service about the facts of the emergency, the steps to be taken by the members of the public actually affected and, the health protection measures applicable for their health protection.

(2) Without prejudice to sub-regulation (1) of this Regulation, when an emergency occurs, the Control Service, in cooperation with other bodies or organisations if required, ensures that 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 for their health protection.

Eighth Schedule Part II

(3) The information provided covers those points listed in Part II of Eight Schedule which are relevant to the type of emergency.

Contaminated areas.

62. –(1) The competent authority, in cooperation with other Services, ensures that optimised protection strategies for managing contaminated areas include, where applicable, the following:

(a) objectives, including long-term goals pursued by the strategy and corresponding reference levels, in accordance with Regulation 6;

(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 where it has been decided to allow habitation and the resumption of social and economic activities, competent authority ensures, 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.

63. –(1) The national reference level for the annual average for indoor radon concentrations is 300 Bq m^{-3}. This national reference level is revised, if this is justified by new scientific data, also taking into account social and economic factors.

(2) Under the national action plan referred to in section 60 of the Law, the Control Service promotes actions to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourages, where appropriate, by technical or other means, radon concentration-reducing measures in these dwellings.

(3) The competent authority ensures that local and 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 existing radon concentrations.

Gamma radiation from building materials.

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

Ninth Schedule

(2) The Control Service identifies building materials which are of concern from a radiation protection point of view, taking into account the indicative list of materials set out in Ninth Schedule with regard to their emitted gamma radiation.

(3) Persons who have or intend to place such materials on the market ensure that:

Tenth Schedule

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

Tenth Schedule

(b) information is provided to the Control Service on the results of measurements and the corresponding activity concentration index, as well as other relevant factors, as defined Tenth Schedule.

(4) For types of building materials identified in accordance with sub-regulation (2) of this Regulation which are liable to give doses exceeding the reference level, the Control Service, where required, decides on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials, in cooperation with the competent services of the Republic.

CHAPTER VIII − GENERAL RESPONSIBILITIES OF COMPETENT AUTHORITY AND OTHER REQUIREMENTS FOR REGULATORY CONTROL

Information on equipment.

65. –(1) Any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided with adequate information from the supplier or manufacturer of the source or radiation generator about its potential radiological hazards and its proper use, testing and maintenance,

and with a demonstration that the design permits restricting exposures to a level which is as low as reasonably achievable.

(2) Any undertaking acquiring medical radiological equipment is provided with adequate information from the supplier or manufacturer of the equipment on the risk assessment for patients, and on the available elements of the clinical evaluation.

Occupational health services.
R.A.A. 330/2017

66. In accordance with the provisions of the Safety and Health at Work (Health Surveillance) Regulations of 2017, as amended or replaced, about employees' health surveillance, occupational health services perform medical surveillance of exposed workers, in accordance with Chapter V of these Regulations, with regard to their exposure to ionising radiation and their fitness for the tasks assigned to them involving work with ionising radiation. The criteria and procedures for the recognition of occupational health services are determined in accordance with section 48 of the Law.

Dosimetry services.

67. Dosimetry services 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, and where relevant the occupational health service. The criteria and procedures for the recognition of dosimetry services are determined in accordance with section 48 of the Law.

Radiation protection expert.

68. –(1) The radiation protection expert acts or/and gives 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) optimisation and establishment of appropriate dose constraints;

(b) 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;

(c) categorisation of controlled and supervised areas;

(d) classification of workers;

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

(f) use of appropriate radiation monitoring instrumentation, regular calibration and inspection of their good condition and proper use;

(g) quality assurance, examination, testing of protection devices or devices and measuring instruments, periodic inspection of the effectiveness of means, techniques and methods of protection devices, techniques and methods of protection and regular inspection of good operation of equipment and to conduct any practice in a way that provides adequate protection against ionising radiation;

(h) environmental monitoring programme;

(i) arrangements for radioactive waste management;

(j) arrangements for prevention of accidents and incidents;

(k) preparedness and response in emergency exposure situations;

(l) training and retraining programmes for exposed workers;

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

(n) employment conditions for pregnant and breastfeeding workers;

(o) preparation of appropriate documentation such as prior risk assessments and written procedures.

(3) The radiation protection expert, where appropriate, liaises with the medical physics expert and the medical physicist of the undertaking. The radiation protection expert may cooperate with the undertaking's radiation protection officer.

(4) The radiation protection expert may be assigned by the undertaking the tasks of radiation protection of workers and members of the public.

(5) The criteria and procedures for the recognition of radiation protection experts are determined in accordance with section 48 of the Law.

Medical physics expert.

69. –(1) The medical physics expert acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements set out in Chapter VI of these Regulations and in paragraph (c) of sub-regulation (4) of Regulation 20.

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

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

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

(c) acceptance testing of medical radiological equipment;

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

(e) the surveillance of the medical radiological installations;

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

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

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

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

(4) The criteria and procedures for the recognition of medical physics experts are determined in accordance with section 48 of the Law.

Radiation protection officer.

70. –(1) (a) The Control Service may decide in which practices the designation of a radiation protection officer is necessary by the undertaking.

(b) The undertakings provide the radiation protection officers with the means necessary for them to carry out their tasks.

(c) The radiation protection officer shall report directly to the undertaking. The employers of outside workers designate a radiation protection officer as necessary to supervise or perform relevant radiation protection tasks as they relate to the protection of their workers.

(2) Depending on the nature of the practice, the tasks of the radiation protection officer, include the following:

(a) ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;

(b) supervising implementation of the programme for workplace monitoring;

(c) maintaining adequate records of all radiation sources;

(d) carrying out periodic assessments of the condition of the relevant safety and warning systems;

(e) supervising implementation of the personal monitoring programme;

(f) supervising implementation of the health surveillance programme;

(g) providing new workers with an appropriate introduction to local rules and procedures;

(h) giving advice and comments on work plans;

(i) establishing work plans;

(j) providing reports to the local management;

(k) participating in the arrangements for prevention, preparedness and response for emergency exposure situations;

(l) providing information and training to exposed workers;

(m) liaising with the radiation protection expert.

(3) (a) 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.

(b) The radiation protection officer cooperates, as appropriate, with the radiation protection expert and the medical physics expert, in the areas of their competence.

General requirements for unsealed sources.

71. –(1) The undertaking maintains unsealed sources under its control and keeps records with regard to their location, use and, when no longer required, their recycling or disposal.

(2) The undertaking, as appropriate and based on the graded approach, keeps records of each unsealed source under its responsibility, including location, transfer and disposal or discharge.

(3) Each undertaking holding an unsealed radioactive source notifies the Control Service promptly of any loss, theft, significant spill, or unauthorised use or release.

General requirements for sealed sources.

72.–(1) The undertaking maintains sealed sources under its control and ensures that arrangements are made for keeping control of sealed sources with regard to their location, use and, when no longer required, their recycling or disposal.

(2) The undertaking keeps records of all sealed sources under its responsibility, including location, transfer and disposal.

(3) The undertaking informs in writing the Control Service of any transfer of high activity sealed sources and where necessary individual transfers of sealed sources.

(4) Each undertaking holding a sealed source notifies the competent authority promptly of any loss, significant leakage, theft or unauthorised use of a sealed source.

Requirements for control of high-activity sealed sources.

73. For issuing authorisation for practices involving a high-activity sealed source, the undertaking ensures that:

(a) adequate arrangements have been made for the safe management and control of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

Specific requirements for licensing of high-activity sealed sources.

74. (1) The activity values that define a high-activity source, as defined in section 2 of the Law, are those provided for in the Eleventh Schedule.

Eleventh Schedule

(2) Subject to the provisions of sections 15 and 21 of the Law, the undertaking ensures prior authorisation by the Control Service for practices relating to high-activity sealed sources.

(3) Subject to the provisions of section 21 of the Law, no person may transfer any source to another person or an authorised facility unless he has obtained prior authorisation from the Control Service.

(4) Without prejudice to the provisions of article (4) of section 20 of the Law, and in addition to the general licensing requirements set out in the Law, the license for a practice involving a high-activity sealed source includes, but does not have to be limited to:

(a) undertaking responsibilities;

(b) minimum undertaking staff competencies, including information and training;

(c) minimum performance criteria for the source, source container and additional equipment;

(d) requirements for emergency procedures and communication links;

(e) work procedures to be followed;

(f) maintenance of equipment, sources and containers;

(g) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

Record keeping by the undertaking.

Twelfth Schedule

75. Subject to the provisions of sub-regulation (2) of Regulation 72, the records for high-activity sealed sources include the information set out in the Twelfth Schedule and the undertaking provides the Control Service with an electronic or written copy of all or part of these records upon request and at least under the following conditions:

(a) without undue delay, at the time of the establishment of such records, which shall be as soon as is reasonably practicable after the source is acquired;

(b) at intervals to be determined by the Control Service;

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

(d) without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal or storage facility to which the source is transferred is included;

(e) without undue delay upon the closure of such records when the undertaking no longer holds any sources;

(f) whenever requested by the Control Service.

The undertaking's records are available for inspection by the Control Service whenever requested.

Record keeping by the Control Service.

76. The Control Service keeps records of any undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. These records include the radionuclide involved, 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 or at the time the undertaking acquired the source, and the type of source. The Control Service keeps the records up to date, taking transfers of the sources and other factors into account.

Control of high-activity sealed sources. Thirteenth Schedule

77. –(1) The undertaking carrying out activities involving high activity sealed sources complies with requirements set out in the Thirteenth Schedule.

Fourteenth Schedule

(2) The manufacturer, the supplier, and each undertaking ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in the Fourteenth Schedule.

Detection of orphan sources.

78.–(1) The managements of large metal scrap yards installations and major metal scrap recycling installations or any other premises or installations in which they are likely to be found or processed orphan sources, or the employers who are responsible for the relevant workplaces, ensure the:

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

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

(2) The managements of installations referred to in sub-regulation (1) of this Regulation as well as the persons responsible for the management of

significant nodal transit points, including customs offices, ensure that employees:

(a) are informed of the possibility of finding or detecting a source;

(b) receive appropriate instructions and training for visual detection of sources and their containers;

(c) receive basic information about ionising radiation and its effects on human health and the environment;

(d) are informed and provided with training on the measures to be taken on the spot in case of finding or detecting a source or if there is a suspicion of finding or detecting a source.

(3) The managements of installations referred to in sub-regulation (1) of this Regulation, or the employers who are responsible for the relevant workplaces, ensure that, during the organisation of information and training activities in the field of radiation protection for orphan sources, this training includes requirements for safe management of sources.

The above information and training:

(a) place particular emphasis on the necessary safety requirements and contain specific information on the possible consequences of the loss of adequate control of sources;

(b) are repeated at regular intervals and documented so that employees are sufficiently prepared for any incidents referred to in sub-regulations (1) and (2) of this Regulation;

(c) addressed to the exposed workers.

(4) The Control Service requires, wherever appropriate, the establishment of systems aimed at detecting orphan sources in places such as large metal

scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, including customs offices.

(5) The management of installations referred to in sub-regulation (1) of this Regulation, ensure that specialised technical advice and assistance is promptly made available to persons who suspect the presence of an orphan source and who are not normally involved in operations subject to radiation protection requirements. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

Metal contamination.

79.–(1) The Control Service requires, wherever appropriate, the establishment of systems to detect the presence of radioactive contamination in metal products imported from third countries, in places such as at major metal importing installations or at significant nodal transit points, such as customs stations.

(2) The management of a metal scrap recycling installation, or the employers who are responsible for the relevant workplaces, promptly inform the Control Service if it suspects or has knowledge of any melting of or other metallurgical operation on an orphan source and shall require that the contaminated materials are not used, placed on the market or disposed of without the involvement of the Control Service.

Recovery, management, control and disposal of orphan sources.

80. –(1) The competent authority establishes:

(a) provisions, including assignment of responsibilities, to control and recover orphan sources and to deal with emergencies due to orphan sources;

(b) appropriate emergency response plans and measures due to orphan sources.

(2) The competent authority ensures that campaigns are organised, as appropriate, to recover orphan sources left behind from past practices.

The campaigns may include the financial participation of the Republic for the costs of recovering, managing, controlling and disposing of the sources and may also include surveys of historical records of Republic's authorities, undertakings, research institutes, material testing institutes or hospitals.

Financial security for orphan sources.

81. −(1) The competent authority ensures that a financial security system or other equivalent means is established to cover intervention costs relating to the recovery of orphan sources and which may result from implementation of Regulation 80.

(2) The Control Service may require from the management of any installation or premise in which it is likely for orphan sources to be found, or the employers who are responsible for the relevant workplaces, including large metal scrap yards installations and major metal scrap recycling installations, in the framework of the system established on the basis of sub-regulation (1) of this Regulation, adequate insurance or other equivalent mean or settlement to cover the intervention cost for the recovery of the orphan sources.

(3) In the case where the last holder of the source is known, before it becomes orphan by negligence or fault of the holder or in case of detection of an orphan source in a premises, installation, area, container or another point for which a specific person is responsible, the Control Service may require that person to pay all or part of the intervention cost for the recovery of the orphan source.

Notification and recording of significant events.

82. The undertaking:

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

(b) promptly notifies the Control Service 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 Control Service for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

PART IX – FINAL PROVISIONS

Repeal.

83. With the entry into force of these Regulations, the following Regulations are repealed:

R.A.A. 494/2002

(a) The Protection from Ionising Radiation (Basic Safety Standards) Regulations of 2002.

R.A.A. 495/2002

(b) The Protection from Ionising Radiation (Information of the Public on Applicable Measures in case of Emergency) Regulations of 2002.

R.A.A. 497/2002

(c) The Protection from Ionising Radiation (Medical Exposure) Regulations of 2002.

R.A.A. 591/2004

(d) The Protection from Ionising Radiation Law of 2002 (Notification under section 10(1)).

R.A.A. 592/2004

(e) The Protection from Ionising Radiation Law of 2002 (Notification under section 7(2)).

R.A.A. 30/2006

(f) The Protection from Ionising Radiation (Control of High Activity Sealed Radioactive Sources and Orphan Sources) Regulations of 2006.

FIRST SCHEDULE

(Regulation 6)

Reference levels for public exposure

1. Without prejudice to reference levels set for equivalent doses, reference levels are set, based on sub-regulation (3)(b) of Regulation 6, expressed in effective dose, as follows:

    (a) in the range of 1 to 20 mSv per year for existing exposure situations; and

    (b) 20 to 100 mSv (acute or annual) for emergency exposure situations.

2. In specific situations, a reference level below ranges referred to in point 1 may be considered, as set out in sub-regulation (1) of Regulation 6, in particular:

    (a) a reference level below 20 mSv 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 1 mSv per year may be set, where appropriate, in an existing exposure situation for specific source-related exposures or pathways of exposure.

3. 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 such as relocation.

4. The reference levels set are taken account of the features of prevailing situations as well as societal criteria, which may include the following:

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

    (b) in the range up to or equal to 20 mSv 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.

SECOND SCHEDULE

(Regulation 18)

Justification of new classes or types of practices involving consumer products

Part I

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

(a) intended use of the product;
(b) technical characteristics of the product;
(c) in the case of products containing radioactive substances, information as to their means of fixation;
(d) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0,1 m from any accessible surface;
(e) expected doses to regular users of the product.

Part II

The Control Service examines that information in Part I and assess whether:

(a) the performance of the consumer product justifies its intended use;
(b) the design is adequate in order to minimise 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;
(c) 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;
(d) тthe product is appropriately labelled and suitable documentation is provided to the consumer with instructions for proper use and disposal.

THIRD SCHEDULE

(Regulation 20)

Indicative list of practices involving non-medical imaging exposure

Part 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.

Part II

Practices not using medical radiological equipment:

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

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

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

FOURTH SCHEDULE

(Regulations 33, 34 and 41)

Data system for individual radiological monitoring

Part I: General Provisions

A data system for individual radiological monitoring is established as a national dose register. This data system includes the issuance of Individual Radiological Monitoring Document for each outside worker, as set out in Fifth Schedule.

1. The data system for individual radiological monitoring of exposed workers comprises the following sections:
    (a) particulars concerning the worker's identity;
    (b) particulars concerning the medical surveillance of the worker;
    (c) particulars concerning the undertaking of the worker and, in the case of an outside worker, the employer of the worker;
    (d) the results of the individual monitoring of the exposed worker.

2. Any forgery or misuse of, or tampering with, the data system for individual radiological monitoring constitutes an offense under section 43 of the Law.

Part II: Data to be provided by the undertaking or employer and entered into the individual radiological monitoring system

1. Data on the worker's identity include the worker's:
    (a) surname;
    (b) first name;
    (c) sex;
    (d) date of birth;
    (e) nationality; and
    (f) unique identification number.

2. Data on the undertaking or the employer include the name, address and unique identification number of the undertaking.

3. Data on the employment of the worker include:

   (a) the name, address and unique identification number of the employer;

   (b) the starting date of individual monitoring; and where available, the end date;

   (c) the categorisation of the worker in accordance with Regulation 30.

4. The results of the individual monitoring of the exposed worker include:

   (a) year;

   (b) effective dose in mSv;

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

   (d) In the event of an intake of radionuclides, the committed effective dose in mSv.

FIFTH SCHEDULE

(Regulation 41)

Individual Radiological Monitoring Document

Part I: Information contained in the Individual Radiological Monitoring Document

1. The issuance of an Individual Radiological Monitoring Document for each outside worker is mandatory.

2. Each Individual Radiological Monitoring Document for an outside worker includes information on:
   (a) identity details;
   (b) the information to be provided before any activity;
   (c) the information to be provided after the activity.

   The identity details of the outside workers shall also include the gender and date of birth of the holder.

3. The Individual Radiological Monitoring Document is not allowed to be transferred to another worker.

4. The issuance of more than one valid Individual Radiological Monitoring Documents at the same time for one worker is prohibited.

5. In addition to the information required in Parts II and III, the Individual Radiological Monitoring Documents includes the name and the address of the issuing body (of the Control Service) and the date of issue.

Part II: Information recorded in the Individual Radiological Monitoring Document

Any employer that employs outside workers provides to the undertaking or employer that has control of the workplace where outside workers will conduct activities or to the recognised, by the Control Service, occupational health service with which the employer or the undertaking cooperates, the following information:

(a) the name, address and unique identification number of the employer who employs the outside workers;
(b) the medical classification of outside workers under Regulation 36;

(c) the data of the medical surveillance of the outside workers, which include the following:

(i) information on any restrictions related to work involving radiation exposure;
(ii) the date of the last periodic medical examination; and
(iii) the period of validity of the result.

(d) the start date of individual monitoring and, if available, the expiration date;

(e) the results of the individual monitoring of the exposure of the outside workers, which include the following:

(i) the exposure time period;
(ii) the effective dose in mSv;
(iii) in the case of non-uniform exposure, the equivalent dose in the various parts of the body in mSv; and
(iv) in the case of radionuclide intake, the committed effective dose in mSv.

Part III: Information recorded in the Individual Radiological Monitoring Document after the end of each activity

Any undertaking that has control of the workplace where outside workers conduct activities records or ensures that they are recorded in the Individual Radiological Monitoring Document of outside workers and sends or ensures that the following information is sent to the Control Service:

(a) the time period of the activity;

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

(c) in case of inhomogeneous exposure, the calculations of the equivalent dose in the various parts of the body;

(d) in case of internal contamination, calculation of the intake or the committed effective dose.

SIXTH SCHEDULE

(Regulation 48)

Written instructions that should be prepared by any undertaking or employer and relate to medical exposures

(a) Instructions for the correct identification of the person to be exposed for medical purposes.

(b) Instructions for identifying individuals authorised to act as referrals, practitioners or operators.

(c) Instructions to be followed in cases of voluntary exposure of individuals for reasons of non-medical imaging.

(d) Instructions for checking whether women of childbearing potential are pregnant or breastfeeding.

(e) Instructions for ensuring that quality control programs are implemented.

(f) Instructions for assessing patients' doses and the activity of the radionuclides administered to them (intake).

(g) Instructions for the use of diagnostic reference levels that are not expected to be exceeded in standard procedures, if appropriate diagnostic and technical practice is used.

(h) Instructions for providing written instructions and information in accordance with sub-regulation (6) of Regulation 46.

(i) Instructions for conducting and recording the evaluation for each medical exposure, and when it is possible to record data on the patient's doses.

(j) Instructions for conducting a clinical audit.

(k) Instructions for ensuring that the probability and magnitude of accidental or unintended doses to patients from radiological practices are maintained at the lowest reasonable achievable levels.

SEVENTH SCHEDULE

(Regulation 49)

Minimum requirements for appropriate training or education of practitioners and operators in radiation protection issues

Practitioners and operators shall have successfully completed training programs, which include theoretical knowledge and practical experience in:

(a) Part I subjects, which are related to their activities as practitioners or operators; and
(b) Part II subjects, which are related to their activities in special radiological practices.

Part I

1. Fundamental radiation physics
   1.1. Properties of radiation
      - attenuation of ionising radiation
      - scattering and absorption
   1.2. Radiation hazards and dosimetry
      - biological effects of radiation
      - risks/benefits of radiation
      - dose optimisation
      - absorbed dose, dose equivalent, effective dose and their units
   1.3. Special topics
      - pregnancy and radiation
      - children and radiation
      - medical and biomedical research
      - health screening of population
      - high dose techniques

2. Management and radiation protection of the patient
   2.1. Patient selection
      - justification of the exposure
      - patient identification and consent
      - use of existing appropriate radiological information for the patient
      - alternative techniques

- clinical evaluation of the exposure outcome
- medico-legal issues

2.2. Radiation protection

- general radiation protection
- use of radiation protection equipment
- patients
- personnel
- procedures for unpleasant incidents involving overexposure to ionising radiation

3. Legislative obligations and counseling or guidance issues

- legislation
- local rules and procedures for each radiological installation
- responsibilities relating to medical exposures
- responsibilities for radiation protection
- daily inspection and testing of equipment
- defective equipment reports
- clinical audit

Part II

4. Diagnostic Radiology

4.1. General

- fundamentals of radiology - anatomy
- fundamentals radiological techniques
- production of X-rays
- equipment selection and use
- factors affecting radiation dose
- dosimetry
- quality assurance and quality control

4.2. Specialised techniques

- fluoroscopy with image intensifier
- digital fluoroscopy
- computed tomography
- interventional procedures
- angiography

4.3. Fundamentals of image acquisition etc.

- image quality versus radiation dose
- conventional film processing
- new methods for development, printing, storage and display

4.4. Image contrast control methods

- non-ionic and ionic
- use and preparation
- media contraindications to the use of contrast media
- use of automatic injection devices

5. Radiotherapy

5.1. General

- production of ionising radiations
- use of radiotherapy
  - benign disease
  - malignant disease
  - external beam
  - brachytherapy
  - radiobiology
  - sealed sources

5.2. Radiological aspects of radiotherapy

- fractionation
- dose rate
- radio sensitisation
- tumour-target data

5.3. Practical aspects for radiotherapy

- equipment
- treatment planning

5.4. Radiation protection especially for radiotherapy

- side effects (immediate and long term)
- toxicity
- assessment of efficacy

6. Nuclear Medicine

6.1. General

- atomic structure and radioactivity
- nuclear reactions
- tracers
- use of radioisotopes for diagnostic procedures
- use of radioisotopes for therapy procedures
    - dose rate
    - fractionation
    - radiobiology aspects

6.2. Radiation measurements, instruments and equipment

- types of measurement systems
- image printing, storage and display
- quality assurance and quality control

6.3. Radiopharmaceuticals products

- calibration
- working methods when using radiopharmaceuticals
- preparation of individual doses
- documentation

6.4. Radiation protection especially for nuclear medicine

- conception, pregnancy and breastfeeding
- arrangements for radioactive patients
- disposal procedures for radioactive waste

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EIGHT SCHEDULE

(Regulations 60 and 61)

Information to members of the public about health protection measures to be applied and steps to be taken in the event of an emergency

Part I: 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.

Part II: Information to be provided to the affected members of the public in the event of an emergency

1. On the basis of the national emergency response plan, 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 are supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

NINTH SCHEDULE

(Regulation 64)

Indicative list of types of building materials considered with regard to their emitted gamma radiation

1. Natural materials

   (a) Alum shale.

   (b) 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.

TENTH SCHEDULE

(Regulation 64)

Definition and use of the activity concentration index for the gamma radiation emitted by building materials

For the purposes of sub-regulation (3) of Regulation 64, 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 are determined.

The activity concentration index I is given by the following formula:

$$I = \frac{C_{Ra-226}}{300}\frac{Bq}{kg} + \frac{C_{Th-232}}{200}\frac{Bq}{kg} + \frac{C_{K-40}}{3000}\frac{Bq}{kg}$$

where $C_{Ra\text{-}226}$, $C_{Th\text{-}232}$ and $C_{K\text{-}40}$ 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 sub-regulation (1) of Regulation 64 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).

ELEVENTH SCHEDULE

(Regulations 74)

Activity values defining high-activity sealed sources

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).

Radionuclide	Activity (TBq)
Am-241	6×10^{-2}
Am-241/Be-9[1]	6×10^{-2}
Cf-252	2×10^{-2}
Cm-244	5×10^{-2}
Co-60	3×10^{-2}
Cs-137	1×10^{-1}
Gd-153	1×10^{0}
Ir-192	8×10^{-2}
Pm-147	4×10^{1}
Pu-238	6×10^{-2}
Pu-239/Be-9[1]	6×10^{-2}
Ra-226	4×10^{-2}
Se-75	2×10^{-1}
Sr-90 (Y-90)	1×10^{0}
Tm-170	2×10^{1}
Yb-169	3×10^{-1}

[1] The activity given is that of the alpha-emitting radionuclide.

TWELFTH SCHEDULE

(Regulations 75)

Information to be provided in the records for high-activity sealed sources (HASS)

STANDARD RECORD SHEET FOR HIGH-ACTIVITY SEALED SOURCES (HASSS)		
1. HASS identification number *Manufacturer device number:* *Field of use:*	**2. identification of licensed undertaking** Name: Address: Country: Manufacturer □ Supplier □ User □	**3. Location of HASS** Name: Address: Country: Fixed use □ Storage □ Mobile use □
4. Recording Date of start of recording: Date of transfer of records to historic file:	**5. License** Number: Date of issue: Date of expiry:	**6. Operational control of HASS** Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date: Date:

<table>
<tr>
<td rowspan="2">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 □
Neutron source target:
Neutron flux:</td>
<td>8. Receipt HASS

Date of receipt:
Receipt from:

Name:
Address:
Country:
Manufacturer □ Supplier □ Another user □</td>
<td>10. Further information
Loss □ Date of loss:
Theft □ Date of theft:
Findings: Yes □ No □
Date:
Place:</td>
</tr>
<tr>
<td>9. Transfer of HASS
Date of transfer:
Transfer to:

Name:
Address:
Country:
License number:
Date of issue:
Date of expiry:
Manufacturer □ Supplier □ Other undertaking □
Facility for long term storage or disposal □</td>
<td>Other information:</td>
</tr>
</table>

* Where the manufacturer of the source is established outside the Community, the name and address of the importer-supplier may be provided instead.

THIRTEENTH SCHEDULE

(Regulations 77)

Requirements for undertakings responsible for a high-activity sealed source

Each undertaking responsible for a high-activity sealed source shall:

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

(b) regularly verify at specific intervals, which may be determined by the Control Service, that each source and, where relevant, the equipment containing the source are still present and in apparently good condition at their place of use or storage;

(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 competent authority of any loss, theft, leakage 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 Control Service 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 competent authority, without undue delay after termination of the use;

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

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

FOURTEENTH SCHEDULE

(Regulation 77)

Identification and marking of high-activity sealed sources

1. The manufacturer or supplier ensures 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 provides a photograph of each manufactured source design type and a photograph of the typical source container.

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