

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

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LAW PROVIDING FOR THE SAFEGUARD AND PROTECTION OF THE HEALTH  
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Preamble. For the purposes of harmonization of the European Atomic Energy Community (Euratom) acts with title–

(a) "Euratom Treaty – articles 30 to 39 provide for the protection of the health of the general public and the workers against dangers arising from ionising radiations."

Official Journal  
of the E.U.: L337,  
5.12.2006, p.21.

(b) " Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel."

Official Journal  
of the E.U.: L172,  
2.7.2009, p.18.

(c) "Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations."

Official Journal  
of the E.U.: L219,  
25.7.2014, p.42.

(d) " Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations."

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

(e) " 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."

and the General Safety Requirements of the International Atomic Energy Agency with title –

(a) "General Safety Requirements No. GSR Part 1 (Rev. 1);

“Governmental, Legal and Regulatory Framework for Safety” (Vienna, 2016)”; and

(b) “General Safety Requirements No. GSR Part 3 “Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards” (Vienna, 2014)”.

The House of Representatives votes as follows:

## CHAPTER I – INTRODUCTORY PROVISIONS

Short title.

1. This Law shall be cited as the Protection from Ionising Radiation and Nuclear and Radiological Safety and Security Law of 2018.

Interpretation.

2. For the purpose of this Law, unless the context otherwise implies:

«applicant» means an undertaking requesting authorisation in writing from the Control Service;

«unintended exposure» means the medical exposure that is significantly different from the medical exposure intended for a given purpose;

«radiation» means the ionising radiation;

«defense in depth» means a hierarchical deployment of different levels of diverse equipment and procedures to prevent the escalation of anticipated operational occurrences and to maintain the effectiveness of physical barriers placed between a radiation source or radioactive material and workers, members of the public or the environment, in operational states and, for some barriers, in accident conditions;

«spent fuel» means the nuclear fuel that has been irradiated in and permanently removed from a reactor core; spent fuel may either be considered as usable resource that can be reprocessed or be destined for final disposal with no further use foreseen and treated as radioactive

waste;

«emergency exposure situation response» means the performance of actions to mitigate the consequences of an emergency for human life, health, property and the environment;

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

«remediation» means any measures that may be carried out to reduce the radiation exposure due to existing contamination of land areas through actions applied to the contamination itself (the source) or to the exposure pathways to humans;

«decommissioning» means the administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility, excluding disposal facilities which mainly include decommissioning and dismantling tasks of the facility or part thereof to reduce the associated radiation risks:

Provided that, a facility could be decommissioned without dismantling and the existing structures subsequently put to another use after decontamination the use of the term decommissioning implies that no further use of the facility or part thereof for its existing purpose is foreseen prior decommissioning;

«decontamination» means the complete or partial removal of radioactivity contamination by a deliberate physical, chemical or biological process;

«discharge» means a planned and controlled release to the environment, as a legitimate practice, of radioactive substances or waste, in gaseous or liquid form, originates from regulated facilities during normal operation, within limits authorized by the regulatory body, of liquid or gaseous radioactive material that originates from regulated nuclear facilities during normal operation, within limits authorized by the Control Service, with the



purpose of their final dispersion;

«absorbed dose (D)» means the energy absorbed per unit mass.

$$D = \frac{d\bar{\varepsilon}}{dm}$$

where:

- $d\bar{\varepsilon}$  is the mean energy imparted by ionising radiation to the matter in a volume element,
- $dm$  is the mass of the matter in this volume element

absorbed dose denotes the dose averaged over a tissue or an organ. The unit for absorbed dose is the gray (Gy) where one gray is equal to one joule per kilogram:  $1 \text{ Gy} = 1 \text{ J kg}^{-1}$ ;

«shipment» means all operations involved in moving radioactive substances or materials or radioactive sources or radioactive waste or spent fuel from the country of origin to the country of destination;

«competent authority» means the Minister and includes any duly authorized Officer of the Ministry having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating the nuclear and radiation safety and security of facilities and radiation sources, the safe management of radioactive waste and transport safety;

«Chief Inspector» means the Chief Inspector appointed under section 30 of this Law;

«safety» means the nuclear and radiological safety;

«accident» means any unintended event the consequences or potential consequences of which are not negligible from the point of view of radiation protection and safety, including nuclear safety or security;

«self-employed person» means a person who works for the purpose of

gain or reward, but is not individually employed by another employer;

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

«environment detriment» means the harmful effects of ionizing radiation on the state of the quality of the environment, whose deterioration may be a threat and have a long-term impact on human health;

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

«notification» means the submission of information to the Control Service where required pursuant to this Law, including to notify the intention to carry out a practice within the scope of this Law;

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

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

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

First Schedule.

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

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

for an intake at time  $t_0$ , where:

- $\dot{H}_T(t)$  is the relevant equivalent dose rate in organ or tissue T at time  $t$ ;
- $\tau$  is the time over which the integration is performed.

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

«disposal» means the emplacement of radioactive substances or radioactive waste or spent fuel in an appropriate disposal facility or specific place without the intention of retrieval;

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

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

«dose» means a measure of the energy deposited by radiation in a target;

«installation» means a nuclear installation; irradiation installations; mining and raw material processing facilities such as uranium mines; radioactive waste management facilities; and any other places where radioactive material is produced, processed, used, handled, stored or disposed of — or where radiation generators are installed — and any other practices or activities in which people may be subject to exposure to radiation from naturally occurring or artificial sources or any other practice within the scope of this Law on such a scale that consideration of nuclear or radiological safety and security and radiation protection is required; the definition includes any premises;

«approved by the Control Service» means approved in writing by the

Chief Inspector or a representative duly authorized by him;

«authorisation» means the registration or licensing of a practice;

«authorisation through licensing» means permission granted in a document by the Control Service, upon request, to carry out a practice or practices or any other activity within the scope of this Law, in accordance with specific conditions and requirements laid down in that document or which this document refers to and includes, inter alia, the transfer of responsibility for siting, design, construction, commissioning, operation, shutdown and decommissioning of an installation;

«national emergency response plan» means a plan prepared based on section 54;

«prohibition notice» means a notice issued based on section 38;

«improvement notice» means a notice issued based on section 37;

«fixed penalty notice» means a notice issued based on section 39;

«import» means the shipment from any country to the Republic;

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

«safety assessment» means a written assessment which includes a collection of arguments and evidence to demonstrate the safety and security levels of an installation, source, practice or activity and radiation protection and it's part of the undertaking's safety assessment report which includes an assessment of all risks of the installation, practice or activity;

«medical exposure» means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research, but does not include exposure of workers or any other persons;

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

«exposure to radon» means exposure to radon progeny;

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

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

«exposed worker» means a person, either self-employed or working under an employer or undertaking or employed as outside worker, full time or part time, permanently or temporarily and who is subject to exposure at work carried out within a practice regulated pursuant to this Law and who is liable to receive doses exceeding one of the dose limits for public exposure;

«risk assessment» means the process and result of systematic analysis and evaluation of risks related to safety, security and protection against ionising radiation in installations, radiation sources or in the conduct of practices and activities;

«disused source» means a sealed source which is no longer used or intended to be used for the practice for which authorisation was granted

but continues to require safe management;

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

«quality control» " means the set of operations regarding programming, coordinating, implementing intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled;

«radiation protection expert» means an individual or a group of individuals having the knowledge, training and experience needed to act or/and give radiation protection advices in order to ensure the effective protection of individuals and compliance with the provisions adopted pursuant to this Law regarding occupational and public exposure, as defined by the Regulations, and whose competence in this respect is recognised by the Control Service;

«medical physics expert» means an individual or a group of individuals, having the knowledge, training and experience to act or/and give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the Control Service;

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

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

$$E = \sum_T w_T \cdot H_T = \sum_T w_T \sum_R w_R \cdot D_{T,R}$$

where:

- $D_{T,R}$  is the absorbed dose averaged over tissue or organ T, due to radiation R,
- $H_T$  is the equivalent doses,
- $w_R$  is the radiation weighting factor and
- $w_T$  is the tissue weighting factor for tissue or organ T

First Schedule.

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

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

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

The unit of activity is the becquerel (Bq);

«export» means the shipment from the Republic in another state;

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

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

«emergency occupational exposure» means emergency worker exposure, which occurs in response to an emergency, in order to save lives or mitigate the health of persons, provide assistance to people at risk, prevent the exposure of large numbers of the public, restrict contamination or spread of radioactive substances, save valuable installations or products or protect property and the environment where dose limits may be exceeded for exposed workers;

«remedial actions» means the removal of a source or the reduction of its magnitude (in terms of activity or amount) for the purposes of preventing

or reducing exposures that might otherwise occur in an emergency or in an existing exposure situation;

«intervention» means any human action intended to reduce or avert exposure or the likelihood of exposure due to sources that are not part of a controlled practice or that are out of control, acting on the sources, the exposure pathways and the individuals themselves;

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

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

«inspection» means investigation, examination, observation, monitoring, measurement or testing by or on behalf of the Control Service to verify compliance with the provisions adopted pursuant to this Law and regulatory requirements or other standards for radiation protection and nuclear or radiological safety and security adopted by the Control Service, including the evaluation of structures, systems, components and materials, as well as the operational activities, technical and organisational procedures, and staff competence;

«Inspector» means inspector appointed according to section 30;

«clearance levels» means values define in this Law or established by the Control Service, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements pursuant to this Law;

«reference level» in an emergency exposure situation or in an existing exposure situation means, the level of effective dose or equivalent dose or activity concentration above which it is judged inappropriate to allow



exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded;

«exemption level» means a value defined by this Law or established by the Control Service and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation based on the provisions adopted pursuant to this Law;

«accelerator» means equipment or installation in which particles are accelerated, emitting ionising radiation with energy higher than 1 mega-electron volt (MeV);

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

«operating lifetime» means the period of use of an installation for its intended purpose and for which authorisation has been granted from the Control Service and commences at the planning stage for the installation siting and ends with the dismantling and remediating of the installation or in the case of a disposal facility, with the closure of the facility;

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

«work» means any project, task, occupation, activity or service that produces a product or result, and provided by employee or self-employed person or outside worker against payment or free or provision of goods or services for profit or non.

Provided that,

(a) employed person is at work throughout his employment as an employed person but not otherwise,

- (b) self-employed person is at work throughout the time dedicated working as a self-employed person,
- (c) outside worker is at work throughout the time spent employed as an outside worker.

It is further provided that the expressions “work”, and “at work” shall be construed accordingly;

«employer» means any person who is responsible for the workplace, the premises, installation and/or facility in which the employee is employed or employed; It is provided that employer includes a person who does not employ any persons, but conducts economic activity or manages the installation for profit or not;

«employee» means a person working or worked under a contract of employment for work execution or a trainee or an apprentice and includes a person who fulfils an alternative social service by virtue of the National Guard Law of 2011 to 2016, or person performing community work at the ordinance on guardianship by virtue of the Guardianship and Other Ways of Addicted Offenders Treatment Law of 1996, as amended or replaced, and a person as inmate of institutions, carry or carried out work assigned to him under the supervision and guidance to employer. the expression "employment" shall be construed accordingly;

19(l) of 2011  
128(l) of 2013  
94(l) of 2014  
2(l) of 2015  
98(l) of 2015  
110(l) of 2015  
82(l) of 2016  
46(l) of 1996.

«internal emergency response plan» means a plan prepared based on section 45(5)(b);

«internal emergency response plan for transport» means a plan prepared based on section 45(5)(c);

«preparedness» in respect of the emergency preparedness means the capability to take actions that will effectively mitigate the consequences of an emergency for human life, health, property and the environment;

«reasonably practicable» in respect of an offense committed in contravention to the provisions of the Law, consisting of the failure of a person to comply with an obligation or requirement to perform a duty according to section 43(5)(d), shall mean, to the extent that the person concerned could not do more than what he did to fulfill the obligation or requirement imposed on him;

«EURATOM» means the European Atomic Energy Community;

«fundamental safety principles» means the fundamental safety principles of the International Atomic Energy Agency (IAEA Safety Standards Series No. SF-1 “Fundamental Safety Principles”, Vienna, 2006), as amended or replaced;

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

«medical exposure» means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers;

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

«equivalent dose ( $H_T$ )» means the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R. It is given by:

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

where:

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

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

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

First Schedule.

The values for  $w_R$  are specified in First Schedule. The unit for equivalent dose is the sievert (Sv);

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

«emergency exposure situation» means a situation of exposure due to an emergency;

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

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

«registration» means permission granted in a document by the Control Service, or granted by national legislation, upon submission of application and through a simplified procedure, to carry out a practice in accordance with conditions laid down in this Law or specified by the Control Service for this type or class of practice;

«risk» means maldistributed quantity expressing hazard, danger or chance of harmful or injurious consequences associated with exposures or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences associated with exposure or potential

exposure to ionising radiation;

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

«high-activity sealed source» means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value laid down in Regulations;

«graded approach» means:

- (a) for a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, and
- (b) an application of safety requirements that is commensurate with the characteristics of the facilities and activities or the source and with the magnitude and likelihood of the exposures;

«public» means members of the public;

«member state of EURATOM» means a Member State of the European Atomic Energy Community;

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

«chronic exposure» means any exposure that lasts for a long time;

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

«transport» means the deliberate physical movement of radioactive

material or radioactive waste or radiation generators or accelerators, from one place to another in the territory of the Republic;

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

«abnormal operation» means a deviation of an operational process from normal operation that is expected to occur at least once during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety or lead to accident conditions;

«safety culture» means the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance;

«security culture» means the assembly of characteristics and attitudes in organisations and individuals which establishes that, the security issues receive the attention warranted by their significance;

«domestic premises» means premises used exclusively as a private dwelling (including any garden, yard, parking place, outhouse or any other auxiliary buildings of such premises or places which are not used in common by the occupants of more than one such dwelling) the expression “non-domestic premises” shall be construed accordingly;

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

«dose limit» means the value of the effective dose (where applicable,

committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual· dose limit values laid down in Regulations;

«contravention» with respect to any provision adopted pursuant to this Law or the Regulations issued under it, includes failure to comply with this provision and the term “contravene” shall be construed accordingly;

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

«period of responsibility» in relation to an undertaking which has been granted authorisation according to section 14, means the period beginning on the day on which it was granted authorisation and ending on the earliest of the following dates:

- (a) the date on which the undertaking is informed in writing by the Control Service that it has ceased to be a risk of being harmed by ionising radiation or a risk of loss of property from the dispersal of radioactive substances derived from anything in the place or from any practice referred to in section 15, or
- (b) the date on which authorisation for any practice referred to in Section 15 is transferred to another person;

«source» means radiation source;

«radiation source» means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material and which can be considered as an entity for safety and security purposes;

«possible exposure» means an exposure which is not expected to be certain, but likely to occur and which can be estimated in advance;

«practice» means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a

planned exposure situation;

«supplier» means any person or organisation to whom a registrant or licensee assigns duties, totally or partially, in relation to the design, manufacture, production or construction of a radiation source;

«radioactivity intake» means the total activity of a radionuclide entering the body from the external environment;

«radionuclides intake» means the radioactivity intake;

«security» means the nuclear or radiological security;

«protection of the environment» means the protection and conservation of:

- (a) non-human species, both animal and plant, and their biodiversity,
- (b) environmental goods and services such as the production of food and feed,
- (c) resources used in agriculture, forestry, fisheries and tourism,
- (d) amenities used in spiritual, cultural and recreational activities,
- (e) media such as soil, water and air,
- (f) natural processes such as carbon, nitrogen and water cycles;

«nuclear installation» means a facility, installation or construction designed or adapted for the performance of any process for the production, enrichment, use, reprocessing, storage and disposal of nuclear fuel and radioactive substances and includes -

- (a) nuclear fission reactors
- (b) storage facilities for radioactive waste
- (c) radioactive waste disposal facilities
- (d) nuclear power plant, an enrichment plant, nuclear fuel fabrication plant, reprocessing plant, research reactor facility, spent fuel storage facility, and
- (e) storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations;



«nuclear or radiological safety» means the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in safety and protection of workers and the general public from dangers arising from ionizing radiations from nuclear or non-nuclear installations respectively;

«nuclear or radiological security» means the prevention and detection of, and response to, criminal or intentional unauthorized acts involving nuclear material or radioactive material, respectively, as well as the associated facilities or associated activities. the term includes theft, sabotage, unauthorized access, illegal transfer or other malicious acts involving nuclear material or radioactive material and their associated facilities;

«nuclear material» means plutonium except that with isotopic concentration exceeding 80% in  $^{238}\text{Pu}$ ;  $^{233}\text{U}$ ; uranium enriched in the isotope 235 or 233; uranium containing the mixture of isotopes as occurring in nature other than in the form of ore or ore residue; any material containing one or more of the foregoing;

«radioactive waste» or waste means radioactive material in gaseous, liquid or solid form for which no further use is foreseen by the competent authority or by the undertaking whose decision is accepted by the competent authority, and which is controlled as radioactive waste by the competent authority under pursuant to this Law and regulatory framework;

«radioactive material» means the material containing radioactive substances;

«radioactive contamination» or contamination means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body and which, in the specific case of the human body, involves both external contamination of the skin and internal contamination, irrespective of the route of intake;

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

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

«radionuclide» means the isotope of any chemical element that emits ionising radiation;

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

«regulatory control» means any form of control or regulation applied to human activities for the enforcement pursuant to this Law and the radiation protection regulatory requirements;

«serious conditions» means conditions that are more adverse than those associated with design-based accidents; such conditions may be caused by multiple failures, such as the complete loss of all components of a safety system, or by an extremely unlikely event;

«activity concentration» means the activity per unit mass of that radionuclide;

«incident» means any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of nuclear and radiological protection, safety or security;

«employment contract» means a contract whether expressed or implied and, if expressed, whether orally or in writing and includes an apprenticeship contract;

«Council» means the Radiation Protection and Nuclear Safety Council established under section 61;

«Counselor» means a person who is appointed under section 30;

First Schedule.

«radiation weighting factor ( $w_R$ )» means a prescribed dimensionless factor used to weight the tissue or organ absorbed dose as specified in First Schedule;

First Schedule.

«tissue weighting factor ( $w_T$ )» means a prescribed dimensionless factor used to weight the equivalent dose in a tissue or organ (T) as specified in First Schedule;

«emergency management system» means a legal or administrative framework establishing responsibilities for emergency preparedness and response, and arrangements for decision making in the event of an emergency exposure situation;

«design base» means the range of conditions and events explicitly taken into account in the design of the installation, including upgrades, in accordance with specified criteria, so that the installation can cope with them without exceeding the authorized limits through its designed operation safety systems;

«emergency response plan» means arrangements to plan for adequate response in the event of an emergency exposure situation on the basis of postulated events and related scenarios;

«closure of the facility» means completing the necessary work in a timely manner, including the final technical or other work required to ensure that the installation is secure and protected in the long run;

«artificial sources» means the radiation sources, other than natural sources;

Second Schedule.  
Part I.

«Technical Licensing Committee» means the Committee established under the Part I of the Second Schedule;

«accidental exposure» means the unintentional and unintentional exposure of persons to radiation as a result of an accident; the term does not include exposure to response in emergency situations;

«radiation protection officer» means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;

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

«Control Service» means the Radiation Inspection and the Control Service that operates under section 7;

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

«premises» means the place where any practice falling within the scope of this Law takes place or is likely to take place and includes:

- (a) any installation on or under land or offshore installation or any other installation whether floating or resting on the sea bed or lake bed or resting on land covered with water,
- (b) any tent or mobile structure, and
- (c) any vehicle, vessel or aircraft;

«Minister» means the Minister of Labour, Welfare and Social Insurances;

«emergency response body or organisation» means any public or private body or organisation assigned with the tasks and responsibilities of the emergency management system according to section 53;

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

«naturally occurring radioactive material» means a radioactive material containing no significant amounts of radionuclides other than naturally occurring radionuclides;

«physical protection barrier» means a physical barrier that prevents or inhibits the unauthorized access of persons, radionuclides or any other phenomenon, such as fire, or provides radiation protection;

«siting» means the process of selecting a suitable site for a facility, including appropriate assessment and definition of the related design bases;

«workplace» includes any place where there are, or there may be present at any time, persons at work;

«becquerel (Bq)» means the special name of the unit of activity. One becquerel is equivalent to one nuclear transition per second:  $1 \text{ Bq} = 1 \text{ s}^{-1}$ ;

«sievert» means the special name of the unit of equivalent or effective dose. One sievert (Sv) is equivalent to one joule (J) per kilogram (kg):

$$1 \text{ Sv} = 1 \text{ J} \cdot \text{kg}^{-1}$$

Application.

3.-(1) This Law applies to:

- (a) any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation or radioactive contamination or releasing or dispersing radioactive substances, which cannot be disregarded from a radiation

protection point of view or with regard to the environment in view of long-term human health protection.

- (b) non-military nuclear installations or installations where ionizing radiation practices take place on the basis of the authorisation required according to section 14.

Provided that the facilities or exposure situations referred to in paragraphs (a) and (b) above also include cases where work is performed by or on behalf of the Republic.

(2) This Law applies in particular to:

- (a) practices or activities such as manufacture, production, processing, handling, use, storage, holding, transport, import, export, shipment, recycling, reuse, discharge and disposal involving radioactive substances or radioactive materials or radioactive waste or radiation generators or accelerators;
- (b) all stages of the installations operational life, such as design, siting, erection, construction, commissioning, operation, maintenance, shutdown, closure, dismantling or decommissioning of the installations;
- (c) the manufacture and the operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);
- (d) human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:
  - (i) the operation of aircraft and spacecraft, in relation to the exposure of crews; and
  - (ii) the processing of materials with naturally-occurring radionuclides;

- (e) the exposure of workers or members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity. Building materials which are of interest in terms of radiation protection are defined by Regulations;
- (f) the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

(3) This Law shall apply without prejudice to the Safety and Health at Work Laws of 1996 to (No. 2) of 2015, as amended or replaced. Further, provided that the definition of the term "undertaking" in this Law and its use in the context of the safety and health protection of workers and general persons at work by ionising radiation does not affect national legal arrangements and the liability of the employer which are provided for in these Laws.

L. 89(I) of 1996  
 L. 158(I) of 2001  
 L. 25(I) of 2002  
 L. 41(I) of 2003  
 L. 99(I) of 2003  
 L. 33(I) of 2011  
 L. 170(I) of 2015  
 L. 178(I) of 2015.

(4) This Law applies to self-employed persons as it applies to undertakings, employers and their employees, as if the self-employed person were both an employer and an employee.

Exclusion from the scope of application.

4. this Law shall not apply to:

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

- (b) exposure of members of the public or workers other than air or space crew to cosmic radiation in flight or in space;
- (c) aboveground exposure to radionuclides present in the undisturbed earth's crust;
- (d) military nuclear facilities.

## **CHAPTER II – COMPETENT AUTHORITY AND NATIONAL REGULATORY FRAMEWORK**

Competent  
authority.

5. The competent authority for conducting the responsibilities, duties and obligations arising from the application of this Law is the Minister.

General  
responsibilities and  
powers of the  
competent authority  
– National  
framework.

6.-(1) The competent authority shall ensure the establishment and maintenance of a national legal, regulatory and organisational framework for all applicable matters of this Law, including the safety and security of installations and radiation sources and the protection against ionising radiation, which shall set out the following:

- (a) the safety principles for protecting people, individually and collectively, society and the environment from radiation risks, both at present and in the future;
- (b) the maintenance and promotion of the continuous improvement of nuclear or radiological safety and its regulation, including national arrangements for a high level of nuclear or radiological safety to protect workers and the general public against the dangers arising from ionising radiations;
- (c) the allocation of responsibilities and provisions for coordination between relevant state bodies in the implementation of this Law;



- (d) the national requirements for ionising radiation and the safety and security of installations, including nuclear safety of nuclear installations, and radiation sources, covering all stages of the life cycle of ionising radiation sources and the operational life of the installations and determining how these requirements are laid down and the means by which they are applied;
- (e) the provision of a system of authorisation and prohibition of operation of nuclear installations without an authorisation;
- (f) assigning prime responsibility for the safety, security and protection from ionising radiation to the undertaking or employer responsible for the practices and facilities and for ensuring the continuity of responsibility where practices are carried out by several undertakings successively;
- (g) provisions for a system for review and assessment of facilities and activities, in accordance with a graded approach;
- (h) provisions for a system of regulatory control for the protection against ionising radiation, the safety, including nuclear safety, and the protection exercised by the competent authority;
- (i) effective and proportionate enforcement actions, including, where appropriate, corrective actions or suspension of operation of an installation or practice and amendment or revocation of an authorisation;
- (j) provision for an interface with nuclear or radiological security and provision for an interface with the system of accounting for, and control of, nuclear material;
- (k) responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities, termination of activities and

remediation;

(l) the criteria for release from regulatory control;

(m) provision for controls on the import and export of nuclear material and radioactive material, as well as for their tracking within, and to the extent possible outside, national boundaries.

(2) The national framework referred to in subsection (1) shall ensure that the competent authority is effectively independent from any undue influence on its regulatory function and regulatory decisions making and that the competent authority:

(a) is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy or ionising radiation or conducting any practices under this Law and employing staff who shall have no direct or indirect interest in undertakings or activities or with persons employed by the undertakings or authorized to act on behalf of such undertakings beyond the interest necessary for regulatory purposes;

(b) does not seek or receive instructions from any other body or organisations in the performance of its regulatory functions. To this end, it is free from any pressures related to political or economic circumstances or other pressures from government services, authorized parties or other organisations;

(c) makes regulatory decisions based on solid and transparent requirements related to the protection from ionising radiation, the safety and security of ionizing radiation sources and nuclear or other installations falling within the scope of this Law;

(d) receives exclusive and appropriate appropriations and has the necessary facilities and equipment to perform its regulatory tasks as defined in the national framework and is responsible for the

use of available funds;

- (e) employs the appropriate number of staff with the required qualifications, experience and expertise to fulfill its obligations;
- (f) establishes procedures for preventing and resolving any conflicts of interest;
- (g) exercises regulatory control consistently and consistently and takes appropriate measures to ensure that regulatory decisions are taken objectively;
- (h) provides information and independent advice and reports on matters related to ionising radiation, safety and security, including access to the highest levels of government, without the approval of another body or organisation, provided that this does not endanger superior interests, such as public security, recognized as such by Law or international acts;
- (j) implements, evaluates and improves, where appropriate, an appropriate management system that complies with, and contributes to, the objectives of protection against ionising radiation, safety and security set by the competent authority itself;
- (k) may supportively uses the services of external technical consultants or any other professional expert service in its areas of competence, without prejudice to its responsibility to exercise its full regulatory duties and obligations.

(3) The competent authority shall have the legal authority to fulfil its statutory obligation in relation to the national framework on the basis of which it is assigned with the following essential regulatory tasks for the purpose of fulfilling the provisions of subsection (1):

- (a) Establishes a national policy and strategy for the safety and

security regarding ionising radiation;

- (b) proposes, sets or participates in the setting of national requirements for the protection from ionising radiation protection, safety, including nuclear safety, and security;
- (c) proposes legislation and/or participates in the preparation of legislation, ensuring compliance with international and European standards on safety, security and protection against ionising radiation, and promotes guidelines and guides for its best and optimum application;
- (d) issues Decrees, Notifications, Codes of Practice, Standards and Specifications for the optimum functioning of the Law;
- (e) requires the undertaking or employer to comply with and document such compliance with national requirements for ionising radiation, safety, including nuclear safety, and security and with the terms, requirements and conditions of relevant authorisation;
- (f) has access, independently or jointly with the undertaking or employer, to the premises of any designer, supplier, manufacturer, contractor or organisation associated with the undertaking or employer, to carry out the necessary controls and requires the above to provide the undertaking or employer with the necessary technical information for the safe management and effective safety and security of radiation sources supplied to the undertaking or employer;
- (g) verifies undertaking or employer compliance through regulatory evaluations and inspections;
- (h) proposes and conducts substantive and proportionate enforcement actions.

(4) The competent authority shall act as a national contact point to promote cooperation and exchange of regulatory experience and information and to communicate with the competent authorities of other EURATOM Member States, the European Commission and other international organisations, and shall transmit contact details as appropriate and its respective competence areas to enable timely communication between them.

Radiation  
Inspection and  
Control Service.

7.(a) The Radiation Inspection and Control Service, hereinafter referred to as the "Control Service", operates under the responsibility of the Ministry of Labour, Welfare and Social Insurances. The Control Service is responsible for overseeing the implementation of this Law.

(b) The Control Service shall be coordinated and supervised by the Chief Inspector appointed under section 30 and who shall be the Head of that Service.

Purpose of the  
Control Service.

8. The Control Service aims at:

(a) protecting the people and workers from hazards in use or exposure to ionising radiation, or hazards from discharge or dispersal of radioactive substances or radioactive contamination, including protection against hazards arising from ionising radiation from nuclear installations, that cannot be disregarded from a radiation protection point of view or with regards to environmental protection, as long as it is aimed at the long-term protection of human health in any exposure situation that falls within the scope of this Law;

(b) maintaining and promoting the continuous improvement of nuclear and radiological safety and security and their regulation with the aim of achieving a high level of nuclear and radiological safety and security.

Responsibilities

9. Subject to the provisions of section 6, the Control Service, among

and powers of the  
Control Service.

other:

- (a) recommends setting safety and security levels for people's health for practices that may cause damage to health due to exposure to ionising radiation, or may cause damage to the environment or result in loss of property due to the release or dispersal of radioactive substances or due to radioactive contamination,
- (b) reviews and assessments of information relevant to safety and security and protection installations and radiation sources and related practices and activities, and the protection of individuals, property and the environment from ionising radiation, to determine whether they comply with regulatory terms, requirements and the conditions specified in the authorization,
- (c) inspects, for the purposes of compliance with this Law, any practices or installations in which activities are conducted that that may cause damage to health or damage to the environment or result in the loss of property due to the release or dispersal of radioactive substances or due to radioactive contamination,
- (d) receives notifications and grants authorisations,
- (e) takes effective and proportionate enforcement actions, including, where appropriate, corrective actions or suspension of operation of an installation or practice and amendment or revocation of an authorisation,
- (f) acts for the coordination of educational, scientific or other organisations responsible for providing advices, education, training and or other relevant services in the field of radiation protection,
- (g) recognizes the ability of experts and services provided for in this Law and persons who may participate in practical aspects of

medical exposures to act in the areas of their competence specified in this Law, as well as the qualifications and training of workers and other persons in safety and radiation protection issues,

- (h) in cooperation with other bodies or organisations where appropriate, ensure the existence, coordination and organisation of the national system as well as planning to prevent or respond to emergencies situations in nuclear or radiological accidents or incidents,
- (i) keeps appropriate records, including records of radiation sources, installations and facilities, practices and exposed workers and doses received,
- (j) recommends the establishment of national safety requirements, including nuclear safety, and their revision, where appropriate, taking into account the experience gained during operation, the lessons learned from on-site safety studies, technology developments and research findings in the field of safety, where relevant and available,
- (k) monitors the levels of radioactivity in air, soil, water, sea, foodstuffs, animal feeding stuffs, building materials and other products and goods through an appropriate environmental monitoring program and ensures that protection measures are implemented when appropriate,
- (l) specifies forms for notification, registration and authorisation and the information provided within, as well as any other forms provided or stemming from this Law,
- (m) cooperates, where appropriate, with external technical support bodies or organisations and Consultants on issues within its competence.

### CHAPTER III – RADIATION PROTECTION FRAMEWORK

Radiation protection principles.

10. For each exposure situation referred to in section 3, a system of radiation protection is established based on the principles of justification, optimisation and dose limitation:

- (a) Justification: Decisions for introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions for introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm. The principle of justification for practices or types of practices and medical exposure is further defined by Regulations.
- (b) Optimisation: Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and social factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in section 56. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions. The principle of optimization for occupational and medical exposure and public exposure is further defined by Regulations.
- (c) Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for



occupational exposure or public exposure. Dose limits shall not apply to medical exposures. Dose limits for occupational exposure, apprentices and students exposure and public exposure are defined by Regulations.

## CHAPTER IV – PROHIBITION AND REGULATORY CONTROL OF PRACTICES

### PART I – PROHIBITION OF PRACTICES

Prohibition of practices.

11.–(1) The deliberate addition of radioactive substances in the production of foodstuffs, animal feeding stuffs and cosmetics, as well as the import or export of such products, is prohibited.

(2) Conducting practices involving the activation of material resulting in an increase in activity in a consumer product, which cannot be disregarded from a radiation protection point of view, as well as the justification of such practices, is further regulated by Regulations.

### PART II – REGULATORY CONTROL

Graded approach to regulatory control.

12.–(1) Practices, sources and installations falling within the scope of this Law are subject to regulatory control for the purposes of radiation protection and radiological or nuclear safety and security, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological or nuclear safety and security of installations and radiation sources.

Third Schedule. (2) Without prejudice to section 14 and 15, where appropriate, and in accordance with the general exemption criteria set out in Third Schedule, regulatory control may be limited to notification and an appropriate frequency of inspections. For this purpose, the Control Service may establish general exemptions or allow the competent authority to decide to exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Third Schedule; in the case of moderate amounts of material, as specified by the Control Service, the activity concentration values laid down in column 2 of Part III of the Third Schedule may be used for this purpose.

Third Schedule.

Third Schedule.  
Part III.

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

Notification.

13.-(1) Subject to the provisions of section 16 any justified practice, including those identified according to section 19, requires the undertaking to notify the Control Service.

(2) The notification shall be made prior to the practice commencing or, for practices existing at the entry into force of this Law, within one year of the entry into force of this Law.

(3) For practices subject to notification, the Control Service specifies the information to be provided in conjunction with the notification.

(4) Where an application for an authorisation is submitted by an undertaking, no separate notification is needed.

(5) The Control Service may exempt a number of practices from the obligation of notification according to section 16.

(6) Notification to the Control Service is required for workplaces where the average annual value of radon concentrations continues to exceed the

national reference level established by Regulations, despite measures taken in accordance with the optimisation principle specified in subsection (2) of section 10 and further defined by Regulations and for existing exposure situations that are managed as a planned exposure situation, as specified in subsection (3) of section 57.

(7) The Control Service may require notification of a practice where, notwithstanding the exemption criteria laid down section 16, it considers that a practice identified according to section 19 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view.

(8) Human activities involving radioactively contaminated material from authorised releases or released material according to section 18 shall not be treated as a planned exposure situation and therefore need not be notified.

Registration or  
licensing.

14.-(1) The Control Service determines the procedures and requirements for authorisation through registration or licensing of practices, including, in any way, the handling, operation, possession, production, storage, transfer, facilitation of transfer, supply, transportation, import, export, shipment, recycling, re-use, disposal or disposal:

- (a) the operation of radiation generators or accelerators or radioactive sources for medical exposures or for non- medical imaging purposes;
- (b) the operation of radiation generators or accelerators, except from electron microscopes, or radioactive sources for purposes not covered by point (a).

(2) Authorisation through registration or licensing shall be granted to the undertaking by the Control Service, in accordance with the procedure referred to in section 17, upon written application by the undertaking to the

Control Service, which in the case of authorisation by licensing will contain or may contain conditions and requirements referred to in section 20.

(3)(a) Subject to the provisions of section 17, for practices requiring authorisation, the Control Service determines the form of authorisation and the information to be provided with the application for authorisation.

(b) The Control Service may, in certain circumstances, including acceptance testing and calibration tests that fall within the scope of this Law, grant authorisation to the undertaking on a temporary basis and for a limited period of time.

(4) The Control Service may also require registration or licensing for other types of practices.

(5) The requirements of section (2) are based on, inter alia, regulatory experience, taking into account the magnitude of expected or potential doses, as well as the complexity of the practice.

Licensing.

15. The following practices require authorisation from the Control Service through licensing:

- (a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;
- (b) the operation and decommissioning of any nuclear facility and the exploitation and closure of uranium mines;
- (c) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products;

- (d) any practice involving a high-activity sealed source;
- (e) the operation, decommissioning and closure of any facility for the long term storage or disposal of radioactive waste, including facilities managing radioactive waste for this purpose;
- (f) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

Exemption from notification.

16. Justified practices involving the following do not need to be notified:

Third Schedule.  
Part III.

- (a) radioactive materials where the quantities of the activity involved do not exceed in total the exemption values set out in column 3, Part III of Third Schedule or higher values that, for specific applications, are approved by the competent authority and satisfy the general exemption and clearance criteria set out in Third Schedule; or

Third Schedule.  
Part II.  
Third Schedule.

- (b) without prejudice to section 13 (4), radioactive materials where the activity concentrations do not exceed the exemption values set out in Part II of Third Schedule, or higher values that, for specific applications, are approved by the Control Service and satisfy the general exemption and clearance criteria set out in Third Schedule; or

- (c) apparatus containing a sealed source, provided that:
  - (i) the apparatus is of a type approved by the Control Service;
  - (ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0.1 m from any accessible surface; and
  - (iii) conditions for recycling or disposal are been specified by the Control Service; or

- (d) any electrical apparatus provided that:

- (i) it is a cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kilo volt (kV), or it is of a type approved by the Control Service; and
- (ii) it does not cause, in normal operating conditions, a dose rate exceeding  $1 \mu\text{Sv}\cdot\text{h}^{-1}$  at a distance of 0.1 m from any accessible surface.

Third Schedule.

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

Authorisation procedure.

17. –(1) For authorisation purposes, the Control Service determines the procedure to be followed referred to in section 14 and the required information relevant to radiation protection and radiological or nuclear safety and security of installations and radiation sources in each case.

Second Schedule.  
Part II.

(2) The procedure for granting authorisation through licensing by the Control Service is defined in Part II of the Second Schedule.

(3) The undertaking applying for authorization through licensing is required to demonstrate and sufficiently substantiate that adequate levels of nuclear or radiological safety, security and radiation protection are maintained at its installation.

(4) The extent and level of details submitted to document the levels of safety, security and radiation protection referred to in subsection (3) are commensurate with the possible extent of and the nature of the radiological hazards at the installation and its characteristics.

(5)(a) Subject to the provisions of subsections (1) to (4) of the authorisation procedure through licensing, the minimum information required to be submitted with the application for authorisation under

Fourth Schedule. subsection (1) is set out in the Fourth Schedule.

(b) In the case that the Control Service considers that the information provided is not sufficient for decision-making, it may request from the applicant additional information and any deadlines set by the Control Service for the completion of the assessment of the application and granting of authorisation will be counted from the submission date of all the information necessary for the assessment of the application and the decision-making.

Release from  
regulatory control.

18.–(1) The disposal, recycling or reuse of radioactive materials arising from any authorised practice is subject to authorisation by the Control Service.

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

Third Schedule.  
Part I.

(a) for solid material do not exceed the clearance levels set out in Part I of Third Schedule; or

Third Schedule.

(b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices set by the Control Service following the general exemption and clearance criteria set out in Third Schedule, and taking into account technical guidance provided by the European Atomic Energy Community.

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

(4) The deliberate dilution of radioactive materials for the purpose of being released from regulatory control is not permitted. The mixing of materials

that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition. The Control Service may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.

Identification of practices involving naturally-occurring radioactive material.  
Fifth Schedule.

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

### PART III – PROCEDURES CONCERNING AUTHORISATION

Terms, requirements and conditions of authorisation through licensing.

20.–(1)(a) The authorisation through licensing referred to in section 15 may include, as appropriate, specific terms, requirements and conditions which the Control Service defines when granting authorisation or subsequently in accordance with section 25, reference to requirements in national legislation so as to ensure that the elements of the license are legally enforceable and impose appropriate restrictions on the operational limits and conditions of operation for which the undertaking or the employer are responsible. The terms, requirements and conditions for granting authorisation take into account, when appropriate, the formal and documented implementation of the principle of optimisation.

(b) Existing practices that fall within the scope of this Law and which require authorisation through licensing may, where appropriate, have placed upon them requirements for the discharge, disposal, recycling or reuse of existing sources or radiation generators or accelerators or other electrical equipment in accordance with the safety requirements provided by this Law or any other applicable Law.

(2) The Control Service may set different dates for the application of the terms, requirements and conditions of authorisation through licensing granted under sections 15 and 17 in the case of undertakings or



employers conducting out any existing practice requiring authorisation on the date of entry into force of this Law.

(3) The granting of other types of approvals or licenses to the undertaking from other government agencies shall not be used as an argument or an advantage towards receiving any authorisation under this Law. Similarly, the need to be granted other licenses from other government agencies, for which any authorisations granted under this Law are considered as prerequisites, may not be used as an argument or in any way be used as an object of coercion to receive authorisations required under this Law.

(4) Without prejudice to the generality of subsection (1), the terms, requirements and conditions will be set accordingly and referred to, inter alia -

- (a) the obligations of the undertaking or the employer,
- (b) the minimum required characteristics of the undertaking or employer in terms of skills and competencies,
- (c) the design and performance criteria and requirements for radiation sources, devices, equipment and other system,
- (d) the risk assessment related to the practice,
- (e) the control of radioactive substances, including the safe management and security of disused radioactive sources,
- (f) the installation and maintenance of effective systems for verifying, measuring and recording the presence and intensity of any form of ionising radiation emitted by anything present in the installation or facility or by anything carried, removed or disposed of there,

- (g) the design, siting, construction, commissioning, operation, modification, maintenance, shutdown or closure of any facility, installation or equipment containing radioactive substances or any radiation generator or accelerator or any nuclear plant,
- (h) the preparations for the response and the measures to be taken in the event of an accident or emergency incident involving ionising radiation,
- (i) the handling, processing, transporting, storing, discharging, disposing, recycling or re-using (as applicable) of radioactive materials and radiation generators or accelerators, and
- (j) the discharge of effluents containing radioactive substances, as regulated by Regulations on radiation protection of members of the public (public exposure), for the purpose of control the release or discharge of effluents containing radioactive substances into the environment,
- (k) the management and transmission of information, including the transmission of information to and from the Control Service, and the degree of confidentiality of such information in relation to, inter alia, the protection of radiation sources.

(5) The Control Service consults on the formulation of the terms, requirements and conditions for granting authorisation according to section 17 the Technical Licensing Committee set out by Part I of the Second Schedule.

Second Schedule.  
Part I.

(6) The Control Service may grant authorisations on the basis of general terms, requirements and conditions for which it has already consulted the Technical Licensing Committee referred to in subsection (5) and shall publish a list of the authorisations and the general terms, requirements and conditions referred to in this subsection.

Prohibition of transferring authorisation.

21. Authorisation granted in accordance with the provisions adopted pursuant to this Law covers only the undertaking to which it is granted and shall not be transferred to another undertaking.

Fees.

22.-(1) The competent authority may determine fees which the undertaking, employer, person or other body is obliged to pay within a specified period, in respect of:

- (a) the receipt, review and assessment of an application for authorisation and which include:
  - (i) costs for registration, or
  - (ii) costs for granting authorisation, or
  - (iii) any renewal, amendment, extension or revocation of the authorisation granted to the undertaking, or
  - (iv) any amendment of the terms, requirements and conditions of authorisation referred to in section 25.

- (b) the provision of reports for judicial purposes.

- (c) covering any expenses incurred by the Control Service, Local Authorities or other bodies or organizations in fulfilling their obligations under the national emergency plan where the undertaking or employer conducts practices or activities that may be harmful the health and safety of the population through an incident of an emergency situation.

- (d) any other service provided or may be provided by the Control Service under this Law.

(2) As provided by this Law, any undertaking, employer, contractor or any beneficiary self-employed, employed or other person may request the Control Service in writing, through a form approved by the Control Service and after paying the determined fees referred to in subsection (1), any:

- (a) documentation, certificate or report;
- (b) approval or recognition of qualifications of persons and of services;
- (c) provision of specialized services such as testing, examinations or audit controls; and
- (d) report of an incident, accident or dangerous event, where such an incident or event has been investigated by the Chief Inspector or Inspector to a sufficient extent to allow a report to be prepared.

which is related to the application of this Law and falls within the competence of the Control Service.

(3) The documents provided to beneficiaries under subsection (2) shall be prepared on the basis of information provided by the Control Service and the payment of any fee does not place it under any obligation to carry out additional investigations, tests, examinations or other work.

Posting or display of authorisation through licensing and its terms, requirements and conditions.

23. The undertaking or employer at any time and whilst the authorisation granted to it is in force, posts or publishes in any form and ensures that it remains posted or published in an appropriate position or a position designated by the Control Service, within the installation and in such printing that is comprehensible by all persons working or present in the installation, a copy of the authorisation together with the terms, requirements and conditions to which this authorisation is subject to in accordance with the provisions adopted pursuant to this Law.

Revocation or surrender of authorisation.

24. Subject to the provisions of sections 25 and 26, any authorisation issued under sections 14, 15 and 17 may at any time be revoked by the Control Service or returned to the Control Service by the undertaking.

Amendment of terms, requirements and conditions of authorisation through licensing and revocation or cancellation of authorisation.

25.—(1) The Control Service sets out the scope and the criteria for the circumstances under which it is justified to amend the terms, requirements and conditions for authorisation through licensing and to withdraw or revoke such authorisation.

(2) Subject to the provisions of subsection (1), the Control Service may, with the exception of situations which cannot be foreseen, amend the terms, requirements and conditions of authorisation through licensing set in accordance to section 20, by adding new or modifying existing terms, requirements and conditions or withdrawing or revoking or cancelling the authorisation.

(3) Where terms, requirements and conditions have been set according to section 20, the undertaking may request that the terms, requirements and conditions be amended at any time.

Instructions after revocation or surrender of authorisation.

26.—(1) In the event of revocation or surrender of the authorisation or at a later stage from the revocation or surrender of the authorisation and until the expiration of the period of liability of the undertaking, the Control Service may give written instructions to the undertaking which are deemed necessary so as to avoid ionising radiation damage or any other situation that has occurred or is occurring in the particular facility or installation.

(2) If the authorisation has been withdrawn or surrendered in accordance with the provisions of subsection (1), the undertaking shall, at the request of the Control Service, surrender or transfer responsibility for the installation for which authorisation has been granted to another undertaking designated by the Control Service. During the remainder of its period of liability, the undertaking displays or ensures that they are displayed to the installation and at such positions that the Control Service may indicate, announcements indicating the restrictions applicable to the installation.

Compensation for revocation or cancellation or amendment of terms, requirements and conditions of license through authorisation.

27.–(1) In the event of revocation or cancellation of an authorisation or in the event of an amendment in the terms, requirements and conditions of authorisation through licensing or the addition of a new term, requirement or condition to the authorisation, within the period of such authorisation or its terms, requirements and conditions are in force, compensation will be paid by the Republic, covering the following:

- (a) in the event of withdrawal of authorisation, the worth of any installation or equipment installed and the worth of any building erected in accordance with the authorisation, which will no longer be able to be used by the undertaking to which the authorisation was granted because of the withdrawal. The compensation does not cover any other losses that may have been caused; or
- (b) in the case of addition of new or amendment of an existing term, requirement or condition, the value of any equipment installed to meet the terms, requirements and conditions of authorisation, in the condition the equipment was prior to amendment and which can no longer be used because of the amendment of terms, requirements or conditions. The compensation does not cover any other loss that may have been caused.

Provided that, in any case, the value shall be calculated at the date of revocation, addition or amendment, net of any value from the resale of the facility, installation or equipment.

(2) The obligation to pay compensation shall not apply if the revocation, cancellation, amendment or addition of a new term, requirement or condition:

- (a) was done with the written consent of the undertaking, or

- (b) it has been demonstrated by the Control Service that it was necessary for the protection of the health and safety of any person, the protection of the environment, the flora or fauna or the protection of property as a result of change in circumstances, including security conditions or political or geopolitical conditions; which could not reasonably have been foreseen at the time the authorisation was granted or at the last time any term, requirement or condition imposed or amendment took place or as a result of new scientific knowledge.

It is provided that the change in circumstances may be a change in the existing scientific knowledge about the possible consequences of the use of ionising radiation.

- (c) was a consequence of modification of the practice for which the authorisation was granted.

Publication of receipt of application for authorisation and record keeping.

28.–(1) The Control Service may determine the practices for which the application for authorisation under section 14 shall be published.

(2) The application for publication referred to in subsection (1) shall be available for inspection at a place and time specified in the publication and any person may submit, within twenty eight (28) days of publication, written suggestions to the Control Service regarding the application.

(3) The Control Service maintains a record showing the details of the installation, including the nuclear installation, in relation to the authorisation granted, as well as all actions, practices and sources related to the authorisation, in accordance with the provisions of section 17.

(4)(a) Subject to the provisions of section 50, the Control Service shall arrange for copies of the record to be made available for public

inspection.

(b) The Control Service may keep confidential and may not publish or make available for public inspection any information that it deems necessary to be kept confidential.

(5) If in the opinion of the Control Service the risk of damage to health by ionising radiation from everything that has been or is being done or has been or is present in any place, facility, installation or nuclear installation for which authorisation is no longer valid, is within defined acceptable levels regarding the protection of members of the public, the relevant information may be deleted from the copies of the Record referred to in subsection (3).

Appeals.

29.-(1) Any undertaking that is affected by -

- (a) the refusal of the Control Service to grant it authorisation, or
- (b) the revocation of a decision in relation to section 17, or
- (c) the terms, requirements or conditions imposed on it in accordance to section 20; or
- (d) the withdrawal of the authorisation granted to it,

may, within twenty eight (28) days from the date the decision referred to in paragraphs (a), (b), (c) and (d) was announced, where appropriate, to appeal to the Minister for such a decision.

(2) The appeal does not suspend the decision referred to in paragraphs (a), (b), (c) and (d) of subsection (1).

(3) The Minister, after studying the appeal, the reasons for the decision and any other information available to him, ratifies, cancels or amends the decision or substitutes it with such a decision which in his opinion



should have been taken initially.

#### PART IV – APPOINTMENT AND POWERS OF CHIEF INSPECTOR, INSPECTORS AND CONSULTANTS

- Appointment of Chief Inspector, Inspectors and Consultants.
- 30.–(1) For the purposes of applying this Law, the Minister appoints a Chief Inspector and Inspectors, as well as any other persons deemed appropriate for the effective implementation of the provisions adopted pursuant to this Law. The Minister may terminate such appointments.
- (2) The Minister may appoint any person as his Consultant in relation to any issues to which this Law applies, as well as terminate the appointment of Consultants. The terms of reference of these Consultants are set out in the appointment form by the Minister.
- (3) The Chief Inspector is in charge of the Control Service and supervises and coordinates overall the activities of the Control Service. The Chief Inspector regulates the cases and how the Inspectors perform their duties and exercise the powers provided to them by this Law.
- (4) The Chief Inspector, the Inspectors and other persons appointed according to this section shall be provided with appropriate identification.
- (5) The person or persons appointed by the Minister under subsections (1) or (2) and who are not civil servants are paid such remuneration as may be determined by the Minister, after consultation with the Minister of Finance.
- Powers of Chief Inspector, Inspectors and Consultants.
- 31.–(1)(a) The Chief Inspector or Inspector appointed according to section 30 has the power, for the purposes of applying this Law, to enter freely and without prior notice into any area, other than residential premises, in which he has reasonable reason to believe that it is necessary to enter at a reasonable time or at any time he believes that there is a situation which may cause immediate danger of serious harm to human health or damage to the environment or serious loss of

property.

(b) Entering a residential premise can be performed after obtaining the consent of the holder, and if the holder does not give his consent, entry can be made after a relevant court order has been obtained.

The areas referred to in this subsection shall include the following:

- (i) the premises or facilities for which application for authorisation has been submitted or for which authorisation has been granted or for which authorisation has been withdrawn or amendment, or
- (ii) areas where it is reasonably suspected of having radioactive substances or radiation generators or accelerators or other electrical equipment falling within the scope of this Law; or
- (iii) areas where equipment related to the use of radioactive substances or radiation generators or accelerators or other electrical equipment falling within the scope of this Law exists or is being manufactured; or
- (iv) installations, including nuclear installations.

(2) The Chief Inspector or Inspector appointed according to section 30 have the power, for the purposes of applying this Law, to perform any or all of the following actions:

- (a) to conduct such examinations, tests, audits, inspections and investigations as may be necessary to ascertain whether there is compliance with the provisions adopted pursuant to this Law and to make arrangements for any other person to conduct such tests, audits and measurements as may be necessary for the exercise of his powers;
- (b) to require that any file, certificate, notification or document held for the purposes pursuant to this Law be presented or sent to him, and any other book or document or digital file necessary to view, for the purpose of any inspection, examination, interrogate or investigate and inspect, examine and copy any of them or to

provide a copy of any of them;

- (c) to require any person for whom he has reasonable cause to believe that can provide information related to any inspection or examination or interrogation or clarification, to answer questions alone or in the presence of any other person who may be allowed to be present and require this person to sign a statement that his answers are true;
- (d) to require any person in the installation or facility or workplace to provide him such amenities and assistance with matters which are under the control or responsibility of such person, as are necessary to assist him for the exercise of his powers according to this section, and in particular to require any person to provide him or any other accompanying person with:
  - (i) safe access to any part of the facility or installation or to any source, and
  - (ii) any means reasonably available for carrying out any tests, measurements, audits, investigations, inspections or examinations deemed reasonably necessary for the exercise of his powers;
- (e) to take such measurements or photographs and make such records as he deems necessary for the purpose of any inspection, examination, interrogation or investigation according to this section;
- (f) to take samples of any objects or substances present in any facility or installation and from the atmosphere inside or near such facility or installation;
- (g) to give instructions that facilities or installations or any part thereof or any device or equipment or source or substance within the facilities or installations remain unchanged for as long as reasonably considered necessary for the purposes of any test,

measurement, examination, investigation or check;

- (h) in the event of the detection of any object, source or substance in any facility or installation for which he had reasonable reason to believe that they may have generated or are likely to generate a radiation hazard, to require their disassembly or submission to any process, restriction, management or testing but not in a way that causes them damage or destruction, unless this is necessary under the circumstances, for the purposes referred to in this subsection;
- (i) in the case of any object or substance referred to in paragraph (k), to seize and retain the object or substance for as long as it is reasonably necessary for any of the following purposes:
  - (i) to examine it or submit it to anything for which he is empowered according to paragraph (k);
  - (ii) to ensure that they are not tampered with before their examination is completed,
  - (iii) to ensure that they are available for use as evidence in any proceedings for an offense under this Law.
- (j) to investigate accidents or serious incidents, as well as illnesses related to the provisions adopted pursuant to this Law, and to seize relevant evidences;
- (k) depending on the situation:
  - (i) to prepare and send letters, reports, approvals, certificates and notes;
  - (ii) to issue approvals, certificates and announcements; and
  - (iii) to issue and serve Improvement Notices, Prohibition Notices and any other notice provided pursuant to this Law.
- (l) to require any person to whom an Improvement or Prohibition Notice is served, to sign such notice and to record at least his name, occupation and/or position in the facility, installation or

undertaking, and also his address.

(3) In addition to the powers referred to in subsection (2)(o), the Chief Inspector or Inspector authorised by the Chief Inspector to act so, according to subsection (7), has the power to issue and serve Fixed Penalty Notice for offenses, violations and omissions as defined in section 39.

(4) If, on the basis of exercising the powers provided to him according to subsection (2)(m), the Chief Inspector or Inspector appointed according to section 30 holds in his possession any object or substance found in any place, leaves a notice to an accountable person or, if this is impracticable, places the notice in a prominent position, providing sufficient information so as to identify the object or substance. Before the Chief Inspector or Inspector takes possession of any such substance he should, if practically possible, take the sample of the substance and hand it over to the accountable person in the undertaking, marked in a manner sufficient for its identification.

(5) When exercising the powers provided to him, the Chief Inspector or Inspector under subsections (1) to (3), may:

- (a) be accompanied by a police officer, if he has reasonable reason to believe that he will be prevented from exercising his powers or performing his duties; in this case the police officer shall be obligated to accompany the Chief Inspector or the Inspector in the event that the Chief Inspector or Inspector so requests;
- (b) be accompanied by any other person and bring with him any equipment or materials necessary for any purpose for which the power to enter the facility or installation is exercised.

(6) Before the Inspector exercises any of the powers provided to him under subsection (2)(l), he consults, if he considers necessary, such

persons as he deems appropriate in order to ascertain what potential hazards may arise if it does what he proposes in accordance with these powers.

(7) Subject to the provisions of subsections (1) to (3), the Chief Inspector has additionally the following powers:

- (i) authorises in writing another person to exercise part or all of his powers, and
- (ii) determines, authorises and makes public the type of forms provided pursuant to this Law, including the Notices referred to in sections 37, 38 and 39.

Protection of  
Inspectors from  
criminal proceeding.

32. No civil or criminal proceedings will be brought against the Chief Inspector or any Inspector or any other person who has or had the powers of an Inspector in relation to anything he did or was ordered to do in good faith under the provisions adopted pursuant to this Law or the Regulations issued pursuant to this Law.

## PART V – REVIEW AND ASSESSMENT OF INFORMATION, INSPECTION AND ENFORCEMENT ACTIONS

Review and  
assessment of  
information relevant  
to safety, security  
and protection from  
ionising radiation.

33.-(1) The Control Service reviews and assess information related to safety, security and protection against ionising radiation, whether submitted by the undertaking or employer or obtained from elsewhere, to determine whether installations, practices and activities performed by the undertaking or employer comply with the regulatory requirements and the terms, requirements or conditions specified in the authorisation.

(2) The review and assessment of this information is carried out initially after applying for authorisation and before granting authorisation, and then during the operational life of the installation or during conducting the practice or activity.

(3) The review and assessment of information for an installation, practice or activity is proportional to the radiation hazards associated with the installation or practice or activity, following the graded approach.

(4) The Control Service during review and assessment of information relating to safety, security and protection against ionising radiation regarding to an undertaking, practice or activity, takes into account the information referred to in Sixth Schedule, following graded approach.

Sixth Schedule.

(5) In order to make a decision, the Control Service reviews, assess and takes into account any other hazards arising from the operation of the installation or the performance of a practice or activity in the undertaking which are not radiation related and which should be included in the safety report referred to in section 45.

(6) The Control Service uses findings from the review and assessment of information related to the safety and security of the installation, sources and practices or activities of the undertaking and the protection from ionising radiation to provide feedback, adjusting accordingly, regarding the procedures governing regulatory control and regulatory decision making.

Inspections.

34.-(1) The Control Service is responsible for implementing an inspection system to enforce the provisions adopted pursuant to this Law its scrutiny and corrective actions, where appropriate.

(2) The Control Service ensures the establishment and the implementation of an inspection programme taking into account the potential magnitude and nature of the hazard associated with installations, sources and practices, a general assessment of safety, security and radiation protection matters in the practices, and the state of compliance with the provisions adopted pursuant to this Law. The inspection programme includes scheduled inspections and re-inspections, both announced and unannounced inspections.

(3) the Control Service records the findings from each inspection and communicates them to the undertaking concerned. If the findings are related to an outside worker or workers or self-employed person, where appropriate, the findings also are communicated to the employer or the self-employed person, respectively.

(4) The Control Service ensures that an overview of the inspection programme and the main findings from its implementation are available to the public.

(5) The Control Service ensures the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections and from reported incidents and accidents and related findings.

Interrogation.

35. –(1) The competent authority may, at its discretion, order an interrogation to be conducted to investigate any accident or catastrophic incident at any installation or facility or premises or workplace or in relation to any source or practice.

(2) The competent authority may, subject to the terms and conditions which it determines, appoint a person or persons having that it deems to have the necessary qualifications, to conduct an interrogation, to investigate an accident or catastrophic incident, and to terminate such appointment.

(3) Any person appointed pursuant to subsection (2) for the purpose of performing interrogations for the investigation of an accident or catastrophic incident shall have all the powers of the Inspector as provided for in section 31.

(4) The person or persons appointed by the competent authority under subsection (2) and who are not civil servants are paid such remuneration as may be determined by the Minister, after consultation with the



Minister of Finance.

Enforcement. 36. The Control Service has the power to require any individual or legal person to take action to remedy deficiencies and prevent their recurrence or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the exposure situation is not in compliance with the provisions adopted pursuant to this Law or the terms, requirements or conditions of authorisation granted according to section 20.

Improvement Notice. 37. If the Chief Inspector or the Inspector is of the opinion that the undertaking or employer:

- (a) violates any provision of this Law or any of the Regulations or Decrees or Code of Practice or Standards or Specifications issued pursuant to this Law or these Regulations, or
- (b) violates any term, requirement or condition of the authorisation granted to the undertaking, or
- (c) violates any such provision in the circumstances that make it possible to continue or repeat the violation,

may issue to the undertaking or employer a notice, referred to as an Improvement Notice, requiring that such undertaking or employer to remedy the violation or, where appropriate, the circumstances causing it, within a period of not less than fourteen (14) days and specified in the Improvement Notice.

Provided that in special cases and if the situation or circumstances leading to a violation so require, at the discretion of the Chief Inspector or the Inspector, the above period may be reasonably decreased to less than fourteen (14) days.

Prohibition Notice. 38.-(1) If the Chief Inspector or the Inspector is of the opinion that any

undertaking or facility or installation or equipment or workspace or any practice or other activity conducted or intended to be conducted at the undertaking, facility, installation, workplace generates a hazard of serious damage to health or serious loss of property or damage to the environment by radiation or, depending on the case, is likely to cause a hazard of serious damage to health or serious loss of property or damage to the environment by radiation or for nuclear or radiological safety and security reasons, may issue to the undertaking or to the employer or to his representatives having responsibility for the facility, installation, equipment or workplace or for the practices or activities conducted therein, a notice, referred to as a Prohibition Notice, prohibiting the use of the facility or installation or the equipment or the workplace or to conduct practices or other activities until the hazard is eliminated, to the extent that the Chief Inspector or the Inspector is satisfied.

(2) The Prohibition Notice applies immediately.

Fixed Penalty Notice. 39.—(1) If the Chief Inspector or Inspector who is authorised by the Chief Inspector to act in accordance with subsection (7) of section 31, is of the opinion that an undertaking or employer violates or has violated any provision of this Law or any of the Regulations or Decrees or Code of Practice or Standards or Specifications issued pursuant to this Law or these Regulations, violates any term, requirement or condition of the authorisation granted to the undertaking has the power to directly fine them by issuing and serving a Penalty Notice.

(2)(a) Subject to the provisions of paragraph (d), the amount of the fixed penalty specified by the Chief Inspector or Inspector acting under subsection (1) is proportionate to the significance of the offense but it cannot exceed the five hundred euros (€ 500) for each violation.

(b) Subject to the provisions of paragraph (a), the maximum accumulated amount of the fixed penalties specified by the Chief Inspector or Inspector acting under subsection (1) in the same Fixed

Penalty Notice cannot exceed the five thousand euros (€ 5.000).

(c) Subject to the provisions of paragraphs (a) and (b), the maximum accumulated amount of the penalties specified by the Chief Inspector or Inspector acting under subsection (1) for a period of two years shall not exceed twenty thousand euros (€ 20.000) for any facility, installation or undertaking.

(d) If the act or omission for which the Chief Inspector or Inspector is acting under subsection (1) is deemed in accordance with subsection (1) to be an offense and is repeated or is not terminated within the timeframe set by the Chief Inspector or Inspector acting pursuant to subsection (1) in the Penalty Notice, then the Chief Inspector or Inspector acting in accordance with subsection (1) shall set a penalty twice the amount set for the first time and if the act or omission is repeated for a third time within two years, then the Chief Inspector takes the necessary steps to prosecute the offender.

(e) Subject to the provisions of paragraph (d), if the act or omission which the Chief Inspector or Inspector acting under subsection (1) considers in accordance with subsection (1) constitutes an offense, is not terminated within the deadline set by the Chief Inspector or Inspector acting in accordance with subsection (1) in the Penalty Notice, then for each day that the act or omission is continued or repeated, it is considered to be a new offense for which the Chief Inspector takes the necessary actions to prosecute the offender:

Provided that, if the offense is repeated a second time or is not terminated within the deadline set by the Chief Inspector or Inspector acting pursuant to subsection (1) in the Penalty Notice, the amount to be determined by the Chief Inspector or Inspector acting pursuant to subparagraph (1) in accordance with paragraphs (a) and (b) of this subsection may not exceed ten thousand euro (€ 10.000).

(3)(a) Any person to whom the Chief Inspector or Inspector acting

pursuant to subsection (1) has issued a Fixed Penalty Notice pursuant to subsections (1) and (2), shall pay the amount stated in the Notice to the Control Service.

(b) The amount referred to in paragraph (a) shall be paid not later than twenty eight (28) days after the date of issue of the Fixed Penalty Notice.

(c) Any amount paid to the Control Service under paragraph (a) shall be deemed to be a penalty imposed for the conviction of the offense concerned.

(d) Subject to the provisions of subsection (2), if the amount referred to in subsections (1) and (2) is paid before the expiration of twenty eight (28) days from the date of issue of the Fixed Penalty Notice, no criminal prosecution may be instituted in connection with the commission of the offense concerned.

(e) Subject to the provisions of subsection (2)(d), following with the extrajudicial settlement of the offense and the payment of the amount to the Control Service, no further criminal proceedings may be instituted for the offense.

(f) The extrajudicial settlement of the offense and the payment of the relevant amount in accordance with the above provisions shall not be considered a conviction:

Provided that, in the case of a conviction by a court for committing another similar offense, the court may consider the above facts for the purpose of determining the penalty for the other offense.

the court may take into account the above facts for the purpose of measuring the sentence for the other offense.

(j) In the event of failure to pay the fees for extrajudicial settlement required by this section by the Chief Inspector or Inspector acting

pursuant to subsection (1), the Chief Inspector takes legal action and collects the amount due as a civil debt due to the Republic.

(4) The Chief Inspector or Inspector acting pursuant to subsection (1), in accordance with the provisions of section 40 of this Law, serves to the undertaking or employer whom he believes has committed the offense the relevant Penalty Notice, specifying the offense and the time of its commission, the period within which the undertaking or employer in question must remedy the offense, as well as the amount of money to be paid.

Service of Notices.

40.—(1) The distribution of the Improvement Notice, Prohibition Notice or Penalty Notice is deemed to be accomplished as soon as the serving is done by the Chief Inspector or the Inspector. If the offender is a natural person, the Notice shall be served either by serving it to him personally or by leaving it to any adult who resides with him or to a person in charge of the place where he resides or of his workplace or occupation.

(2) If the violation is committed by a legal person or by a cooperative or a consortium or organisation, the Notice is served at the central workplace of the legal person or the cooperative or consortium or organisation in the Republic or, delivered:

- (i) to one of the partners, or
- (ii) to the director, or
- (iii) to the secretary, or
- (iv) to the principal representative in the local jurisdiction, or
- (v) to anyone in charge of the business of the legal person or of the cooperative or organisation at the time of service.

(3) The serving of each Notice is demonstrated either verbally by the server or by with his sworn statement.

Withdrawal or extension of Notice.

41. —(1) The Improvement Notice may be withdrawn by the Chief Inspector or the Inspector at any time or the period specified therein may be extended at any time, provided that no appeal to the Notice is

pending.

(2) The Prohibition Notice may be withdrawn by the Chief Inspector or the Inspector at any time.

Appeals against  
Notices.

42.–(1)(a) Any undertaking or employer who considers that he has been wronged by any Improvement Notice or Prohibition Notice or Fixed Penalty Notice may appeal through a written application to the Minister for revocation or amendment of the Improvement Notice or Prohibition Notice or Fixed Penalty Notice.

(b) In such a case, the Improvement Notice, Prohibition Notice, or Fixed Penalty Notice shall continue to apply, as well as the deadline set in the Notice, unless the Notice is revoked or amended by the Minister.

(2) The appeal under subsection (1) shall be submitted not later than fourteen (14) days after the issue of the Notice.

(3) The Minister decides whether or not to accept the appeal and any revocation or amendment of the Notice within fourteen (14) days of the submission of the appeal to the Minister.

Offences, penalties  
and legal  
procedures.

43.–(1) Any undertaking or employer subject to obligations under this Law who fails to comply with any provisions of this Law or the Regulations issued thereunder, is guilty of an offense and subject to a fine not exceeding eighty thousand euros (€ 80.000) or to imprisonment not exceeding four (4) years or to both.

(2) Any undertaking or employer who violates:

(a) a decree issued by a Court of Justice, or

(b) a term of the authorisation or other document issued under this Law, or

- (c) a term issued by the competent authority or the Control Service or authorisation granted under this Law, or
- (d) any obligation or prohibition imposed by the Improvement Notice or Prohibition Notice or Fixed Penalty Notice, including any notice that has been amended following an appeal, or
- (e) any requirement that the Chief Inspector or Inspector may have on the basis of the powers provided to him according to section 31, or
- (f) to comply with any provision of a Code of Practice, Standard or Specifications, approved and issued pursuant to section 63, unless proven to the Court, and the Court is satisfied that the provisions of the Code of Practice, Standard or Specifications have otherwise been complied with,

is guilty of an offense and, if convicted, is liable to a fine not exceeding eighty thousand euros (€ 80.000) or to imprisonment not exceeding four (4) years or both.

(3) Any person who:

- (a) deliberately delays or impedes the Chief Inspector or Inspector in the exercise of his powers or in the performance of his duties under this Law; or
- (b) interferes with or attempts to prevent any other person from presenting himself to the Chief Inspector or the Inspector or answering any question to which the Chief Inspector or the Inspector may require an answer; or
- (c) knowingly or intentionally makes a false statement in order to demonstrate that he complies with any obligation to provide any information required by this Law or any Decree or

Regulations issued pursuant to this Law; or

- (d) intentionally signs or makes a false entry in any file, notice book or other document or digital file required to be recorded or supplied under this Law or uses any such record that is known to be untrue in order to mislead; or
- (e) falsifies, distorts or alters any certificate or document required under or for the purposes of this Law or any Decree or Regulation issued pursuant to this Law; or
- (f) issues or signs such a certificate knowingly that it is fallacious with respect to any essential element; or
- (g) presents or uses a certificate that is knowingly falsified or false with respect to any essential element; or
- (h) knowingly presents or uses certificates related to any undertaking or person which do not concern that undertaking or person; or
- (i) represents a person named on such a certificate; or
- (j) falsely pretends to be an Inspector; or
- (k) deliberately consents to the above forgery, signature, use, counterfeiting or pretense; or
- (l) discloses any information in violation of section 50; or
- (m) fails to notify or apply for authorisation in accordance with sections 13, 14, 15 and 17

is guilty of an offense and, if convicted, is liable to a fine not exceeding forty thousand euros (€ 40.000) or to imprisonment not exceeding two



(2) years or both.

(4)(a) The Court may, when imposing the penalty it considers appropriate to any undertaking or person, in addition to the imposition of a penalty, to issue an Order requiring the undertaking or person to comply with this Law within such time period as may be specified in the Order.

(b) If the violation continues even after the expiry of the period initially specified in the Order or extended by an amending Order, then that person or undertaking will be subject to a fine not exceeding two thousand euros (€ 2.000) or imprisonment not exceeding one (1) month or both, for each day for which such violation continues.

(5)(a) This section also applies to persons serving in the Public Service or in a public utility company and who have obligations under this Law and fail to comply with any provisions of this Law or the Regulations issued thereunder, as it applies to other persons.

(b) When the offense committed under this Law by persons serving in the Public Service or in a public utility company is shown to have been committed with the consent or cooperation or that its commitment has been facilitated by negligence on the part of any Head of Department or other person serving in the Public Service or, in the case of a public utility company, the Director General, Director or a representative, these persons shall be considered guilty of an offense and shall be liable to prosecution and punishment.

(c) A legal person is liable for the offenses provided for in this Law, when committed by any natural person acting either individually or as a member of a collective body of the legal person and holding a leading position in that legal person or has a power of attorney to represent the legal person or on the basis of his power to exercise control within the legal person and in such a case the responsibility for committing the offense is placed, in addition to the legal person, and to the natural

person referred to above.

(d) In any proceedings for an offense committed in violation of any of the provisions of this Law, which consist of the failure of a person to comply with an obligation or requirement to perform a duty, as long as such compliance is practically or reasonably practicable, it is the defendant's responsibility to prove that it was not practically achievable or not reasonably achievable to do more than he did to fulfill the obligation or requirement imposed on him.

## **CHAPTER V – PRIME RESPONSIBILITY AND OBLIGATIONS OF UNDERTAKINGS OR EMPLOYERS OR OTHER PERSONS**

Prime responsibility for the safety and security of facilities and radiation sources and the protection from ionising radiation.

44.–(1) The undertaking or employer responsible for a facility or practice has prime responsibility for the safety and security of the facility and radiation sources and the protection against ionising radiation.

(2)(a) The prime responsibility of the undertaking or employer referred to in subsection (1) includes the obligation to apply the general principles of radiation protection provided for in section 10 of this Law, as well as compliance with national legislation, authorisation and any other regulatory requirements designated or approved by the competent authority.

(b) Compliance with the national legislation, the authorisation or other regulatory requirements designated or approved by the competent authority does not relieve the undertaking or employer responsible for a facility or practice of the primary responsibility for safety, security and radiation protection.

(3) The undertaking or employer retains prime responsibility for the safety, security and radiation protection throughout the lifetime of facilities and the duration of activities, and shall not delegate this prime

responsibility. Responsibility for safety, security and radiation protection may be transferred to a different authorised undertaking when the Control Service has been notified for the transfer of general responsibility for a facility or practice and if such change is approved by the Control Service.

(4) Responsibility for safety, security and radiation protection may extend to other persons or groups associated with the undertaking or employer, such as designers, suppliers, manufacturers, employers, contractors, and consignors and carriers, in so far as their activities or products may be of significance for safety, security and radiation protection. However, in no case this extension of responsibility relieves the undertaking or the employer of the prime responsibility for safety, security and radiation protection. The undertaking or employer has the responsibility for verifying that products and services coming from persons or groups meet his expectations, such as the suitability, completeness, validity, authenticity, robustness, durability or quality of the manufacture of the products or or services and that such persons or groups comply with applicable legal and regulatory requirements.

(5) Subject to the provisions of subsection (3), the prime responsibility for safety extends to all stages in the lifetime of facilities and the duration of activities, i.e. to site evaluation, design, construction, commissioning, operation, shutdown and decommissioning of facilities, or in the case of disposal facilities for radioactive waste the shutdown and the closure, until their release from regulatory control.

This prime responsibility for safety includes, as appropriate, responsibility for the management of radioactive waste and for the remediation of contaminated areas. It also includes responsibility for activities in which radioactive material and radioactive sources are produced, used, stored, transported or handled.

(6)(a) The undertaking or employer responsible for a facility or an activity, having prime responsibility for safety, security and radiation protection actively evaluates advancements in science and technology

as well as relevant information from the gain and exchanges of experiences, in order to identify and to make those safety, security and radiation protection improvements that are considered practicable.

(b) Such improvements in safety, security and radiation protection may require notification to or authorisation from the Control Service under this Law.

(7) The undertaking or employer who is responsible for facilities or activities in which radioactive waste is generated has responsibility for safety, security and radiation protection in the management of the radioactive waste, including waste characterisation and storage of the radioactive waste.

(8) For ensuring safety, security and radiation protection in the transport of radioactive material, the consignor of a radioactive material package has the responsibility to ensure the appropriate selection of the package and packaging and the mode of transport.

(9) The responsibility of the undertaking or employer for the security of facilities and radiation sources covers, inter alia, the minimisation of the possible loss of control of the facilities or sources or of commitment of an act of sabotage or other unlawful act, immediate actions to recover control of the orphan sources in case of loss of control and cultivation and continuous improvement of the security culture.

Responsibilities of the undertakings or employers, self-employed persons and the designers, manufacturers, importers and other persons.

45.-(1) Each undertaking or employer shall take all necessary technical, organisational and administrative measures, subject to the authorisation granted under section 14 of this Law, to ensure the safety and security of installations and radiation sources and the safety and protection of the health of any person and the protection of the use of any person's property and the environment.

(2) (a) Subject to the provisions of section 44(3), the undertaking or

employer may delegate to other persons the performance of actions or the taking of actions related to his/her obligations under this Law, but the undertaking or employer shall have responsibility for such activities, actions or omissions of such persons and shall always have the prime responsibility for radiation protection and nuclear or radiological safety and security.

(b) In the case of an undertaking or employer:

- (i) permits another undertaking, employer or self-employed person to carry out work on the premises, facility or installation thereof, or
- (ii) outsources part of his work to another undertaking, employer or self-employed person,

then the undertaking or employer shall, as far as reasonably practicable, before carrying out or outsourcing such work, to:

- (i) ensure that the other undertaking or employer or self-employed person, as the case may be, is able to apply or maintain at least the same levels of safety and protection of the health of workers in the premises, facility or installation thereof;
- (ii) ensure that the other undertaking or employer or self-employed person has, where appropriate, an appropriate safety and risk management system in place, as well as an adequate and sufficient written risk assessment;
- (iii) ensure that the other undertaking or employer or self-employed person, where appropriate, has the necessary knowledge and experience, as well as the necessary documents, licenses or certificates to perform the work properly.

(3) The undertaking or employer, whenever he intends to make amendments to any practice or facility for which he has obtained authorisation, notifies the Control Service in writing, providing the Control Service with the information required to fully describe the nature and other elements of the amendment. Where such amendments have or may have a significant effect, as judged by the Control Service, on issues of nuclear or radiological safety, security and protection against ionising radiation, the protection of the use of any person's property and the protection of the environment, then the undertaking or the employer shall obtain new authorisation for this before proceeding with the amendments.

(4) (a) –

- (i) Each undertaking or employer conducts itself or ensures that a written risk assessment has been carried out, indicating that all risks likely to lead to an accident have been identified and the nature and magnitude of any potential impacts on employees or other persons, on facilities, radiation sources, property and the environment have been identified.
- (ii) The risk assessment shall be reviewed whenever significant changes occur in the current practices or in the available knowledge or experience.
- (iii) The risk assessment shall be recorded in an appropriate safety report. The safety report contains, at the least, the information referred to in Part I of the Seventh Schedule.

Seventh Schedule.

Part I.

(b) If the risk assessment referred to in paragraph (a) of this subsection indicates that there is a risk to the health of employees or other persons, to facilities, radiation sources or to property or the environment from an accident that may occur, the undertaking or employer takes all appropriate measures for:

- (i) the avoidance of such an accident;
- (ii) limiting and mitigating the consequences in the event of such an accident.

(c) The Control Service may, if it considers it appropriate, request the undertaking or employer to carry out a more detailed risk assessment within the safety report, taking into account the information referred to in Part II of the Seventh Schedule.

Seventh Schedule.

Part II.

(d) The risk assessment and the monitoring of the effectiveness of the safety and security measures implemented by the undertaking or employer in relation to facilities and radiation sources shall be carried out at various stages, including the siting decision, design, construction, building, beginning of operation, operation, maintenance, shutdown and dismantling or demolition of an installation under the responsibility of the undertaking or employer, as appropriate, for the purpose of:

- (i) identifying the way in which persons are or are likely to be exposed to ionising radiation;
- (ii) identifying ways in which safety and security of facilities and radiation sources are affected or are likely to be affected;
- (iii) identifying the way in which loss of property or the effect or probability of adversely affecting the property or the environment occurs or is likely to occur.

Provided that, factors related to sources and other related electrical equipment, as well as external factors independent of sources will be taken into account;

- (iv) determining the level of any normal exposure;
- (v) determining the probability of any exposure occurring and the magnitude of any potential exposure; and
- (vi) assessing the quality and effectiveness of safety and security measures and the safe operation of sources and related electrical equipment.

(5) (a) Whenever a risk assessment based on subsection (4) indicates that a radiation emergency situation may be created, the undertaking or employer prepares an appropriate written emergency response plan designed to limit any person's exposure to radiation and the protection of the environment.

(b) The emergency response plan, prepared in accordance with paragraph (a) of this subsection, which relates to any radiation installations or sources, referred to as the "internal emergency response plan", is prepared based on the principles set out in Part III of the Seventh Schedule and contains at least the information listed in Subpart A of Part IV of the Seventh Schedule.

Seventh Schedule.  
Part III.  
Seventh Schedule.  
Part IV.

(c) The emergency response plan, prepared in accordance with paragraph (a) of this subsection, relating to the transport of radioactive substances or materials and referred to as the "internal emergency response plan for transport", is prepared based on the principles set out in Part III of the Seventh Schedule and contains at least the information referred to in Subpart B of Part IV of the Seventh Schedule.

Seventh Schedule.  
Part III.  
Seventh Schedule.  
Part IV.

(d) The emergency response plans referred to in paragraphs (a), (b) and (c) of this subsection are:

- (i) reviewed and revised, if necessary;
- (ii) periodically tested at appropriate intervals, taking into account any changes in the practices performed, the knowledge and experience available and the risk assessment on which their preparation was based; and
- (iii) submitted for evaluation to the Control Service.

(6)(a) Subject to the obligation of the undertaking or employer in accordance with subsection (5) to prepare an emergency response plan, the undertaking or employer shall make emergency preparedness and response arrangements.

(b) Emergency arrangements include in particular:

- (i) procedures, guidelines and arrangements to deal with accidents that can occur in all operating, shutdown and transitional situations, ensuring consistency and continuity between all



these processes and arrangements, and ensuring that they are tested, reviewed and updated;

- (ii) sufficient in number and trained staff, adequate and sufficient equipment and other necessary resources;
- (iii) an organisational structure with a clear allocation of responsibilities, as well as coo
- (iv) coordination between the undertaking itself and the emergency response agencies or organisations;
- (v) clear assignment of responsibility for the immediate notification of the emergency situation to the Control Service and to the emergency response agencies or organisations; and
- (vi) arrangements for receiving external assistance.

(7)(a) Each undertaking or employer ensures that only persons entitled or described by their knowledge or their qualifications in the application and the authorisation, where required by the Control Service, have been assigned with important tasks related to the safety and health protection of any person, the protection of property in use and the protection of the environment, and that only workers who have been assigned such duties which include the operation or use of sources and which may significantly affect the safety and health of persons or the protection of property or the protection of environmental protection shall perform such tasks.

(b) The undertaking or employer takes into account the job-related qualifications, skills, education and training of that worker when assigning tasks to his employee. When it comes to outsourcing a job to a worker, the undertaking or employer ensures that this person has sufficient knowledge and experience of the work to be performed so that he can perform this task without risk to himself or to other persons.

(8) Each undertaking or employer establishes an appropriate administrative and management system, depending on the size of the undertaking, installation or practice for which it has been granted authorisation, which ensures that, inter alia:

- (a) there is policy and procedures that demonstrate that safety, security and protection against the dangers arising from the use of ionising radiation are his priorities;
  - (b) the dangers arising from the use of ionising radiation for the health and safety of persons, for the use of property and for the protection of the environment are timely detected and corrective actions according to the level of risk are taken;
  - (c) the responsibilities of each person as well as their decision making powers in respect to safety, security, health and safety of persons or the protection of the use of property or the protection of the environment are clearly defined and these persons are appropriately educated and trained and have necessary qualifications;
  - (d) there is continuous information and guidance on safety, security and protection against ionising radiation at all levels of undertaking operation;
  - (e) where practicable, radiation sources under the responsibility of the undertaking or employer become identifiable and traceable or, where this is not practicable, there are alternative procedures for identifying and tracing those sources;
  - (f) where radioactive sources are stored for an extended period of time, subject to authorisation by the competent authority, the facility in which they are stored is suitable for this purpose;
  - (g) appropriate and up-to-date records of the sources and practices are kept and are available to the Control Service.
- (9) Each undertaking or employer applies the measures provided for in this Law and the Regulations issued pursuant to this Law in accordance

with the following general preventive principles:

- (a) risks avoidance;
- (b) assessment of risks that cannot be avoided;
- (c) combating risks at their source;
- (d) adaptation of work to the person, in particular in terms of sitting position placements and selection of work equipment and working methods;
- (e) monitoring the technology development;
- (f) replacement of the hazardous by the non-hazardous or the least hazardous;
- (g) developing a unified and comprehensive prevention policy covering technology, work organisation, working conditions, relationships between the involved parties and the impact of factors related to the work environment;
- (h) prioritization of collective protection measures, without undermining the implementation or adoption of individual protection measures;
- (i) providing appropriate guidance to persons at work.

(10) Every undertaking or employer has quality assurance programs in place that ensure, as appropriate:

- (a) suitable safeguards that the measures applied or safety, protection and protection against the dangers of ionizing radiation are satisfactory;

(b) quality control mechanisms and procedures for assessing the effectiveness of the measures; and

(c) regular assessments, verifications and continuous improvement, as far as reasonably practicable, of the safety of their installations in a systematic and verifiable manner. These include the verification of the existence of accident prevention measures and mitigating the consequences of accidents, including verification of the application of defense in depth provisions.

(11)(a) The undertaking or employer takes appropriate steps to cultivate, promote and maintain effective safety and security culture at all levels of personnel and the management of the undertaking itself, as a key factor in achieving a high level of safety and security, which is constantly improving.

(b) Actions taken by the undertaking or employer to cultivate an effective safety and security culture include in particular:

- (i) the commitment at all levels of personnel and management of the undertaking to safety and security and its continuous improvement;
- (ii) the improvement of the capacity of personnel at all levels to judge whether principles and practices are provided to continually improve safety and security;
- (iii) the ability of personnel to report on safety and security matters in a timely manner;
- (iv) lessons learned from the installation's operating experience;
- (v) systematically reporting any deviations from normal operating conditions and the arrangement for management measures for accidents that have the potential to affect safety and security.

(c) The undertaking or employer takes into account to his/her actions to achieve a strong safety and security culture the following:

- (i) effective management systems;
- (ii) appropriate education and training;

- (iii) arrangements enabling him/her to record, evaluate and document internal and external operational experience related to safety and security and to effectively resolve issues that arise; and
- (iv) reporting to the competent regulatory authority any incidents that have potential implications for safety and security.

(12) Subject to the provisions of section 47, all undertakings or employers shall ensure that personnel responsible for the safety, security and protection from ionising radiation is properly trained and qualified to understand its duties and perform them, responsibly and in accordance with established procedures. Training and monitoring of personnel qualifications is repeated periodically as appropriate.

(13)(a) Each undertaking or employer, in cooperation with manufacturers or suppliers, as far as reasonably practicable, shall follow the principles of ergonomics in the design of equipment, jobs and operating procedures to ensure safety, protection of human health and the environment and also to minimize the risk of accidents.

(b) The undertaking or employer shall ensure that all necessary measures are taken to ensure that the work equipment, devices and tools made available to his/her workers are suitable for the task to be performed or adapted for this purpose, in order to ensure the safety and security of human health and the environment during their use.

(14) Every undertaking or employer ensures that the necessary equipment, safety systems and procedures are in place, which:

- (a) reduce, as far as reasonably practicable, the possibility of human error that may result in exposure for any person, loss of property or radioactive contamination of the environment,
- (b) detect and correct human errors in a timely manner, and
- (c) facilitate intervention in the event of an accident.

(15) Each undertaking or employer consults radiation protection experts on issues falling within the areas of their competence as defined by Regulations issued under this Law, and notifies the Control Service in writing of any arrangements it has made to the provisions of this subsection. The undertaking or employer ensures that the radiation protection experts whom he consults are adequately trained and qualified in accordance with the provisions of section 47 of this Law.

(16) Every undertaking or employer is required to:

- (a) ensures, under the regulatory control of the Control Service, regular evaluation, verification and continuous improvement to the extent reasonably practicable, of the radiological safety of installations where ionising radiation practices are conducted and the nuclear safety of nuclear installations in a systematic and verifiable manner.
- (b) verify the application of accident prevention measures and mitigates the consequences of accidents, including the verification of physical barriers and intrinsic safety measures, as well as administrative procedures to protect the undertaking, the failure of which can lead to significant exposure of workers and the population to ionising radiation;
- (c) establish and implement appropriate administrative and management systems which give due priority to nuclear and radiological safety and security. In order to achieve the objective of safety in this subsection, an undertaking or employer ensures, inter alia, that:
  - (i) he minimizes the impact of extreme natural and unintended anthropogenic hazards;
  - (ii) he prevents abnormal operation and failures;
  - (iii) he monitors for abnormal operation and detects failures;

- (iv) the resulting accidents occurring within the design base are under control;
  - (v) serious circumstances conditions are under control, including the prevention, development of accidents and mitigation of the effects of serious accidents;
  - (vi) organizational infrastructures for on-site emergency preparedness and response have been set up, with clear allocation of responsibilities and coordination between the undertaking and the competent authority and the emergency response agencies or organizations, taking into account all phases of an emergency in accordance with subsection (6).
- (d) (i) he provides and maintains sufficient financial resources, including alternative means of demonstrating its financial competence, human resources, with appropriate qualifications and responsibilities, and technical means to fulfill his obligations with regard to the radiological safety and security of an installation or the nuclear safety of a nuclear installation or the protection of radiation sources as defined by this Law;
- (ii) he provides that the responsibility of his/her contractors and subcontractors whose activities may affect the safety and security of an installation to have the necessary human resources, with the appropriate qualifications and abilities, to fulfill their obligations.
- (e) complies with the Codes of Practice, Standards and Specifications approved and issued pursuant to section 63 of this Law.

(17) Subject to the provisions of section 3(4), the provisions of this section similarly apply to self-employed persons.

(18)(a) Any worker who practices or participates in an activity that is subject to the provisions of this Law:

- (i) takes reasonable care for the health and safety of himself and of other persons who may be affected by his acts or omissions when performing the practice or participating in the activity;
- (ii) without prejudice to the prime responsibility of the undertaking or employer in accordance with section 44, cooperates with the undertaking or employer in carrying out any duties or obligations imposed on them under this Law;
- (iii) uses the protective equipment or clothing provided by the undertaking or the employer in accordance with the provisions of this Law without delay and appropriately and reports immediately to the undertaking or his employer any deterioration or reduced performance of the equipment is noted.

(b) No person shall intentionally or unintentionally misuse or arbitrarily interfere with anything provided for the safety, health and welfare of himself or others persons when practicing or engaging in an activity that is subject to the provisions of this Law.

(19) Any undertaking designing, manufacturing, importing, supplying, renting or propagates any facility for conducting any practice or activity that is subject to the provisions of this Law or that produces, manufactures, imports or supplies any radiation source shall:

- (a) ensures that the source and/or installation is designed and constructed so that it is safe and without risks to the health and safety of any persons and to the protection of the environment when conducting with or in them any practice or activity by any person;
- (b) conducts or arranges for such tests or examinations as may



be necessary to fulfill the obligations imposed on that person by the provisions of paragraph (a);

- (c) take such measures as to ensure that adequate information has been provided to the persons he has supplied the source or installation on the use for which they were designed or tested and on any conditions that ensure that they are safe and without risks to safety, health protection and the environment in all cases referred to in paragraph (a) and in cases where the source or installation is dismantled, decommissioning, dissolved or discharge;
- (d) take such measures as to ensure, as far as reasonably practicable, that the persons to whom he supplied the source or installation, all revisions to the information provided under paragraph (c) are provided so as to make it known if any serious risk is present.

Measurements.

46.–(1) Every undertaking or employer ensures that:

- (a) he conducts any measurements necessary; and
- (b) continuous monitoring, measurement or recording of the necessary parameters exists

for the purpose of complying with the provisions of this Law.

(2) Any instruments, methods or procedures for measuring or monitoring or recording used for compliance with the provisions of subsection (1) shall be appropriate, properly maintained and controlled and periodically calibrated in accordance with the manufacturer's instructions and/or accepted by the Control Service protocols.

(3) The results of the measurements, monitoring or recordings referred to in subsection (1), including control data or calibrations of the

measuring instruments, shall be kept by the undertaking or employer in an appropriate file.

(4) Any measurements, monitoring or recordings conducted by the Chief Inspector or the Inspectors designated pursuant to section 30 or on their behalf for the purpose of checking compliance with the provisions of this Law shall be considered as admissible testimony in any judicial proceeding.

## **CHAPTER VI – GENERAL RESPONSIBILITIES OF COMPETENT AUTHORITY AND OTHER REGULATORY CONTROL REQUIREMENTS**

### **PART I – EXPERTISE AND COMPETENCES AND RECOGNITION OF SERVICES AND EXPERTS**

Expertise and competences.

47.-(1) All relevant parties take such care so that their staff members who have competences or obligations and responsibilities relating to the protection from ionising radiation, radiological and nuclear safety and security of installations and radiation sources receive education and training, in order to acquire, maintain and further develop their expertise and skills on these matters and on-site emergency preparedness.

(2) The competent authority establishes a legislative and administrative framework ensuring the provision of appropriate education, training and information in radiation protection and nuclear safety and security to all individuals whose tasks require specific competences in these matters.

(3) The framework referred to in subsection (2) ensures, inter alia, that:

(a) Any person providing education or training programs in the issues referred to in subsection (2) and issuing certificates of attendance for their programmes, shall clearly specify in these certificates the level and modules covered, the duration of education and/or training in each module, the date of the

education and/or training event and the name of the education provider.

- (b) Any person providing the education and/or training programs referred to in paragraph (a) and issuing attendance certificates for such programmes, may carry out the education and/or training activities in the specific subject areas only if he has sufficient and appropriate knowledge and experience in these matters recognized as such by the Control Service.
- (c) The certificates referred to in paragraphs (a) and (b) are issued subject to special provisions which may be laid down by the Control Service, including relevant provisions in Codes of Practice, Standards and Specifications approved and issued pursuant to section 63.

(4) The framework referred to in subsection (2) ensures the provision of training and information is repeated at appropriate intervals and documented.

(5) The competent authority ensures that arrangements are made for the establishment of education, training and retraining to allow the recognition of radiation protection experts and medical physics experts, as well as occupational health services and dosimetry services referred to in section 48, in relation to the type of practice.

(6) The competent authority may make arrangements for the establishment of education, training and retraining to allow the recognition of radiation protection officers, and in accordance with the provisions of section 48(3).

Recognition of services and experts.

48.–(1) The competent authority sets out the criteria and procedures for the recognition of the following services and experts:

- (a) occupational health services;

- (b) dosimetry services;
- (c) radiation protection experts
- (d) medical physics experts.

(2) The areas of competence for which the above services or experts may be required to provide services are defined by Regulations.

(3) The Control Service may lay down criteria and procedures for the recognition of radiation protection officer, whose areas of competence are also defined by Regulations.

(4) The competent authority ensures that the necessary arrangements are in place to ensure the continuity of expertise of these services and experts.

(5) The competent authority specifies the recognition requirements of subsection (1) and communicates them to the European Commission.

## PART II – TRANSPARENCY AND PROTECTION OF INFORMATION

Transparency.

49.–(1)(a) The Control Service ensures that information in relation to the justification of classes or types of practices, the regulation of radiation sources and of radiation protection is made available to undertakings, workers, members of the public, as well as patients and other individuals subject to medical exposure.

(b) This obligation includes ensuring that the Control Service provides information within its fields of competence.

(c) Information is made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, the nuclear or radiological

safety and security, recognised in national legislation or international obligations.

(2) necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation.

(3) The provisions of subsection (2) include the obligation of the competent authority and the undertakings, within their fields of responsibility, to provide in the framework of their communication policy -

- (a) information on normal operating conditions of nuclear installations to workers and the general public; and
- (b) prompt information to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation in case of incidents and accidents.

(4)(a) Information shall be made available to the public in accordance with relevant legislation and the international instruments of the Republic, provided that this does not jeopardise other overriding interests, such as public security, which are recognised in relevant legislation or international instruments.

(b) To inform the public and make information available quickly and efficiently, the competent authority uses the most appropriate means in each case, such as publications or announcements in newspapers or television and radio stations of Pancyprian and/or local broadcasting, use of posters, use of email, postings on the website of the competent authority and providing copies to the offices of the local authorities concerned.

(5) Without prejudice to section 6 (4), the competent authority engages, as appropriate, in cooperation actions on the nuclear safety of nuclear installations with competent regulatory authorities of other EURATOM Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.

(6) the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international instruments of the Republic.

Protection of  
information.

50.—(1) No person discloses any information relating to a commercial, industrial or medical secret obtained during the exercise, either by himself or by another person, of the powers provided by this Law.

(2) The obligation under subsection (1) not to disclose information relating a trade, industrial or medical secret does not apply:

- (a) if the undertaking or employer of the premises responsible for the equipment or facility from where the information was obtained gives written consent; or
- (b) if there is a relevant non-confidentiality clause in a form or application submitted for the purposes of applying this Law and no specific protection of the information provided is stated; or
- (c) for the purposes of applying any of the provisions of this Law; or
- (d) for the purposes of criminal proceedings for an offense under this Law; or
- (e) for the purpose of any investigation carried out by or on behalf of the competent authority, in relation to the

application of any of the provisions which it is obliged to apply.

(3) Notwithstanding the provisions of subparagraph (1), the Chief Inspector or Inspector may, in any premises or facilities, where it is necessary to do so for the purposes of providing adequate information to employees or their representatives or to their employer or self-employed persons, provide them on matters affecting their safety, health and well-being with the following descriptive information:

- (a) Events relating to such premises or facilities or to the activities performed in the premises or facilities; and
- (b) in relation to any measures which he has taken or intends to take in relation to such premises or facilities in the performance of his duties.

(4) Notwithstanding the provisions of subsection (1), the Chief Inspector or Inspector may provide the information referred to in subsection (3)(a) to any person or undertaking affected by the above events or to their authorised representative, provided that the information is requested in writing by the affected person or company or their authorised representative and will be used for judicial purposes.

### PART III – PEER REVIEWS AND REPORTING

Peer review.

51.–(1)(a) The competent authority shall, at least once every 10 years, arrange for periodic self-assessments of the national framework referred to in section 6 and the competent authority, and invite an international peer review of a suitable peer with the aim of continuously improving nuclear safety.

(b) Outcomes of such peer reviews shall be reported to EUTARTOM Member States and the European Commission, when available.

(2) The competent authority ensures that, on a coordinated basis –

- (a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on the territory of the Republic;
- (b) all other EURATOM Member States, and the European Commission as an observer, are invited to peer review the national assessment referred to in paragraph (a);
- (c) appropriate follow-up measures are taken for relevant findings resulting from the peer review process;
- (d) relevant reports and its main outcomes are published on the above mentioned process when they are available.

(3) The competent authority ensures that arrangements are in place to allow for the first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.

(4) In case of an accident leading to situations that would require off-site emergency measures or protective measures for the general public, the competent authority ensures that an international peer review is invited without undue delay.

Reporting.

52. By 22 July 2020, the competent authority shall submit a report to the European Commission on the implementation of the provisions of this Law harmonizing national legislation with Directive 2009/71 / Euratom, as amended.

#### PART IV – EMERGENCY EXPOSURE SITUATIONS

Emergency management system.

53.-(1) The competent authority, in co-operation with other emergency response agencies or organisations, where appropriate, shall take all



necessary measures to ensure that:

- (a) account is taken of the fact that emergencies may occur within the territory of the Republic and that the Republic may be affected by emergencies occurring outside its territory;
- (b) an emergency management system and adequate administrative provisions to maintain such a system are established;
- (c) the emergency management system includes the elements listed in Part I of the Eighth Schedule.

Eighth Schedule.  
Part I.

(2)(a) The emergency management system referred to in subsection (1) is designed to:

- (i) be commensurate with the results of an assessment of potential emergency exposure situations, and
- (ii) be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events.

(b) The competent authority is responsible for the final assessment of potential emergencies within or outside the territory of the Republic. The competent authority is also responsible for assessing emergency conditions and the impact on the occurrence and development of an emergency, as well as assessing the exposure of members of the public, emergency workers and other population groups and the implementation of appropriate measures.

(c) The competent authority may use the infrastructures and arrangements under the environmental monitoring program referred to in section 9 or other relevant infrastructures of other agencies for the purpose of assessing an emergency.

(3) The emergency management system referred to in subsection (1) provides for the establishment, review and update of emergency response plans with the objective of avoiding reactions in tissues leading to severe deterministic effects in any individual from the affected population and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels specified by Regulations.

(4) The competent authority further takes all necessary measures to ensure that:

- (a) members of the public and employees are informed in a timely manner of the dangers and protection measures in the event of an emergency;
- (b) there are special teams for technical, medical and hygiene care in case of emergency situations;
- (c) interventions are organised to respond to emergencies with regard to the source, the environment and humans, taking into account the specificities, assessment and recording of the consequences of the situation and the effectiveness of the intervention;
- (d) reference levels are set which are guidance levels in case of emergency response interventions and which may on exception be exceeded for saving lives and only by volunteers who are aware of the dangers to their health from their intervention.

(5) The procedures relating to emergency occupational exposure, information and training of emergency workers and information to members of the public who may be affected in an emergency or who are actually affected in an emergency are defined by Regulations issued pursuant to this Law.

Emergency  
preparedness.

54.—(1) The competent authority ensures that emergency response plans are established in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations.

Eighth Schedule.  
Part II.

(2) The national emergency response plan(s) referred to in subsection (1) include the elements set out in Part II of Eight Schedule.

(3) The national emergency response plan(s) referred to in subsection (1) also include provision for the transition from an emergency exposure situation to an existing exposure situation.

(4) The competent authority ensures that emergency response plan(s) are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national and international level and the experience gained from testing or activating the plan(s).

(5) The national emergency response plan(s), where appropriate, incorporate relevant elements of the emergency management system referred to in section 53.

(6)(a) The national emergency response plan(s) referred to in subsection (1):

- (i) utilise to its advantage the competences and responsibilities of the stakeholders involved during normal conditions beyond emergency situations; and
- (ii) it is distributed to all parties involved.

(b) The parties involved in the national plan(s) referred to in paragraph (a) are required to:

- (i) harmonise the individual action plans under their supervision with the national plan(s); and
- (ii) take all necessary measures, including the availability in numbers,

quality and time, of the necessary human resources and technical means to establish and maintain the required infrastructure and preparedness and response procedures.

It is provided that these measures have a relevant provision in the financial budgets of the parties involved.

International  
cooperation in  
emergency  
exposure situation  
response.

55.-(1) The competent authority, in cooperation, where appropriate, with the Ministry of Foreign Affairs and the diplomatic missions of the Republic abroad, ensures that the Republic cooperates with other Member States and with third countries in addressing possible emergencies within its territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in those Member States or third countries.

(2) The competent authority, in the event of an emergency occurring within the territory of the Republic or likely to have radiological consequences within the territory of the Republic, ensures, in cooperation with the Ministry of Foreign Affairs and the diplomatic missions of the Republic abroad, that the Republic promptly establishes contact with all the other EURATOM Member States and with third countries which may be involved or are likely to be affected with a view to sharing the assessment of the exposure situation and coordinating protective measures and public information by using, as appropriate, bilateral or international information exchange and coordination systems. These coordination activities shall not prevent or delay any necessary actions to be taken on a national level.

(3) The competent authority, in cooperation with the Ministry of Foreign Affairs and the diplomatic missions of the Republic abroad, ensures that the Republic promptly shares information and cooperates with other relevant EURATOM Member States, relevant third countries and relevant international organisations regarding the loss, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related follow-up or investigations, without prejudice to relevant confidentiality requirements and relevant national

legislation.

(4) The competent authority, in cooperation with the Ministry of Foreign Affairs and the diplomatic missions of the Republic abroad, where appropriate, cooperate with other Euratom Member States and with third countries in the transition from an emergency exposure situation to an existing exposure situation.

Radiological and nuclear accidents.

56.–(1) If a radiological or nuclear accident involving or affecting any practice, activity, facility or nuclear installation for which authorisation has been granted under this Law occurs or an accident occurs during the transport of radioactive substances, the undertaking or employer immediately inform the Control Service and any other services or persons referred to in the authorisation or have been communicated in any way to the undertaking or employer.

(2) In the event of a radiological or nuclear accident or an accident during the transport of radioactive substances as referred to in subsection (1), the Control Service determines, as specified in the emergency response plan(s) referred to in section 54 or if it is not specified as it deems appropriate, the period during which the area in which the risk of harm to human health or the loss of property or damage to the environment due to the accident exceeds the established acceptable levels for the protection of the public and workers.

(3) The Control Service records the names of all persons who, according to the information available to them, are within the area designated as described in subsection (2) and other specific information relating to the investigation of the accident in relation to each person.

## PART V – EXISTING EXPOSURE SITUATIONS

Programmes on existing exposure situations.

57.–(1) The Control Service ensures that measures are taken, upon indication or evidence of exposures that cannot be disregarded from a radiation protection point of view, to identify and evaluate existing

Ninth Schedule.

exposure situations taking into account the types of existing exposure situations listed in the Ninth Schedule, and to determine the corresponding occupational and public exposures.

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

(3) Existing exposure situations which are of concern from a radiation protection point of view and for which legal responsibility can be assigned shall be subject to the relevant requirements for planned exposure situations. Such exposure situations shall be required to be notified as specified in section 13.

Strategies for the management of existing exposure situations.

58.—(1) The Control Service establishes strategies to ensure the appropriate management of existing exposure situations commensurate with the risks and with the effectiveness of protective measures.

(2) Each strategy referred to in subsection (1) includes, inter alia:

- (a) the objectives pursued;
- (b) appropriate reference levels, taking into account the reference levels laid down in Regulations.

Implementations of strategies for the management of existing exposure situations.

59.—(1) The Control Service implements the strategy(ies) for the management of existing exposure situations, and ensures appropriate coordination between relevant parties involved in the implementation of remedial and protective measures. Stakeholders are involved as appropriate in decisions regarding the development and implementation of strategies for managing exposure situations.

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

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

(4) The Control Service ensures that those responsible for the implementation of a strategy(ies) referred to in section 58, under the supervision of the Control Service, shall regularly:

- (a) evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures;
- (b) provide information to exposed populations on the potential health risks and on the available means for reducing their exposure;
- (c) provide guidance for the management of exposures at individual or local level;
- (d) with regard to activities that include radioactive materials and are not managed as planned exposure situations, provide information on appropriate means for monitoring concentrations and exposures and for taking protective measures;
- (e) inform the Control Service of the relevant results.

Radon action plan. 60.-(1) In application of section 57, the competent authority establishes a national action plan addressing long-term risks from radon exposures in dwellings, buildings with public access and workplaces for any source of radon ingress, whether from soil, building materials or water. The action plan shall take into account the matters set out in Tenth Schedule and be updated on a regular basis.

Tenth Schedule.

(2) The action plan ensures that appropriate measures are in place to prevent radon ingress into new buildings. These measures may include specific requirements in national building regulations.

Action measures are communicated to all stakeholders with a view to harmonising the action plans under their supervision.

(3) The Control Service identifies areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant national reference level established by Regulations.

## **CHAPTER VII – RADIATION PROTECTION AND NUCLEAR SAFETY COUNCIL**

Radiation  
Protection and  
Nuclear Safety  
Council.

61.–(1) The Minister may, by Decree published in the Official Gazette of the Republic, establishes a Radiation Protection and Nuclear Safety Council, hereinafter referred to as "the Council".

(2)(a) The Council is chaired by the Chief Inspector or his representative and its members and their term of office are also defined in the Ministerial Decree referred to in subsection (1).

(b) The Minister has the power to appoint another member of the Council, for a specified period, to replace a member of the Council who resigns before the end of his term of office. In addition, the Minister, if he considers it appropriate, has the power to replace any member of the Council for a period to be determined by himself.

(3) The Council advice the Minister–

(a) on formulating a national policy for radiation matters, including the application of nuclear techniques, nuclear or radiological safety and health and safety matters against the dangers arising from ionising radiation;



- (b) on all matters relating to radiation or nuclear energy, including matters relating to potential exposure to radiation from dangers coming from sources outside the Republic; and
- (c) on any other matters within his competence it deems appropriate.

## CHAPTER VIII – FINAL PROVISIONS

Issuance of Regulations.

62.–(1) The Council of Ministers, upon the recommendation of the Minister, may issue Regulations on any matter that needs to be regulated in order to better implement and achieve the purposes of this Law.

Eleventh Schedule.

(2) Without prejudice to the generality of subsection (1), the Regulations may, inter alia, provide for any of the purposes set out in the Eleventh Schedule.

Code of Practice, Standards and Criteria.

63.–(1) The Control Service, for the purpose of providing practical guidance on the obligations imposed by this Law and any Regulations issued thereunder, may approve and issue Codes of Practice, Standards and Specifications suitable for the purpose and which may, at any time, as it deems appropriate, revise, modify, or withdraw.

(2) In the event of a criminal proceeding under this Law, failure by any person to comply with any provision of the Code of Practice, Standard or Specification approved and issued pursuant to subsection (1), constitutes an offense under section 43.

Repeal.  
L. 115(I) of 2002  
L. 8(I) of 2009  
L. 127(I) of 2011  
L. 122(I) of 2017.

65. With the entry into force of this Law, the Protection from Ionising Radiation and Nuclear Safety Laws of 2002 to 2017 are repealed.

Transitional provisions.

66. any Regulations, Ordinances, Notices or other Regulatory or Individual Administrative Acts that were prepared or promulgated under

the repealed Laws and which were in force immediately prior to the entry into force of this Law, are deemed to have been or have been issued under this Law and shall continue to apply, except to the extent that they are contradictory with this Law, until amended or replaced –

- (a) any Regulations, Ordinances, Notices or other Regulatory or Individual Administrative Acts that were made or promulgated under the repealed Laws and which were in force immediately prior to the entry into force of this Law, are deemed to have been or have been issued under this Law and shall continue to apply, except to the extent inconsistent with this Law, until amended or replaced;
- (b) any licenses or authorisations, including the terms, requirements or conditions accompanying them, were granted under the repealed Laws and were valid and effective immediately prior to the entry into force of this Law, shall be deemed to have been granted under the relevant provisions of this Law; and shall continue to be valid and effective unless and until they are canceled, suspended, expired or renewed pursuant to the provisions of this Law;
- (c) the existing, immediately before the entry into force of this Law, Radiation Protection and Nuclear Safety Council, will continue to operate and exercise the powers and duties of the Council established under section 61 of this Law, and its existing members will continue to hold their position as if they were appointed under this Law until the term of office for which they were appointed;
- (d) any Registry kept by the Control Service under the repealed Laws shall continue to be kept under this Law, introducing where necessary the changes necessary to comply with the relevant provisions of this Law;

- (e) any document, plan, program or report issued under the repealed Laws and referring to any provision of those Laws, remains in force and shall be construed as referring to the relevant provision of this Law;
- (f) any fees that have been issued under the repealed Laws and were in effect prior to the entry into force of this Law, shall be deemed to have been enforced under this Law and shall remain in force until they are repealed or revised;
- (g) all appointments under the repealed Laws of Chief Inspector and Inspector, which were valid prior to the entry into force of this Law, shall be deemed to have been made under this Law and shall continue to have such effect;
- (h) any requests to the competent authority under the repealed Laws, the review of which is pending at the date of entry into force of this Law, shall be handled and decided in accordance with the provisions of this Law;
- (i) in the event that any deadline provided for in the repealed Laws has been initiated and continues to exist at the time of entry into force of this Law and there is a corresponding provision in this Law, this Law shall apply as if that corresponding provision had entered into force at the time this period or period started.

**FIRST SCHEDULE**

(Section 2)

**Radiation and tissue weighting factors.**A. Radiation weighting factors

<u>Radiation type</u>	<u>WR</u>
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, $E_n < 1 \text{ MeV}$	$2,5 + 18,2 e^{-[\ln(E_n)]^2/6}$
Neutrons, $1 \text{ MeV} \leq E_n \leq 50 \text{ MeV}$	$5,0 + 17,0 e^{-[\ln(E_n)]^2/6}$

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

B. Tissue weighting factors

<u>Tissue</u>	<u>WT</u>
Bone-marrow (red)	0,12
Colon	0,12
Lung	0,12
Stomach	0,12
Breast	0,12
Remainder tissues <sup>1</sup>	0,12
Gonads	0,08
Bladder	0,04
Oesophagus	0,04
Liver	0,04
Thyroid	0,04
Bone surface	0,01
Brain	0,01

Salivary glands	0,01
Skin	0,01

(<sup>1</sup>) The  $w_T$  for the remainder tissues (0,12) applies to the arithmetic mean dose of the 13 organs and tissues for each sex listed below. Remainder tissues: adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

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## SECOND SCHEDULE

(Sections 2, 17 and 20)

### PART I: Technical Licensing Committee

1. –(a) A technical committee is hereby set up, called the "Technical Licensing Committee", which shall advise the Control Service on licensing issues. The Committee is represented by a representative from the following Ministries:

- (i) Ministry of Labour, Welfare and Social Insurances, through the current representative of the Control Service;
- (ii) Ministry of Agriculture, Rural Development and Environment;
- (iii) Ministry of Health;
- (iv) Ministry of Interior;
- (v) Ministry of Energy, Commerce, Industry and Tourism;
- (vi) Ministry of Transport, Communications and Works.

(b) Each Ministry referred to in paragraph (a) shall:

- (i) appoint a liaison for the functioning of the Technical Licensing Committee, which may also be the Ministry's representative in the Committee;
- (ii) may send different representatives to the various meetings of the Technical Licensing Committee and the non-continuous attendance of Committee meetings by the same Ministry representative may not be used as a pretext for active or inactive participation of the representative at the meeting or the ability to express an opinion or formulating a recommendation to the Committee. Each representative may be accompanied by a maximum of two scientific or technical advisors.

2. Issues related to terms, requirements and conditions for granting authorisation under section 17 are discussed in the Committee. The Committee may discuss general terms, requirements and conditions for authorisation through licensing as referred to in section 17.

3. –(a) The Technical Licensing Committee will be chaired by the representative of the Ministry of Labour, Welfare and Social Insurances, through the current representative of the Control Service.

(b) Quorum will consist of three members of the Technical Licensing Committee, including the Chairman of the Committee.

Provided that, a Ministry that is justifiably prevented in exceptional cases from being represented at a meeting may send any of its views in writing to the Chairman of the Committee on the matters under discussion prior to the beginning of that meeting.

(c) If a representative of any of the Ministries involved or the Ministry itself has any direct or indirect involvement or self-interest or legal or other interest in connection with any matter discussed with the Committee, then that representative abstains from the vote or does not attend the meeting or the part thereof, as appropriate, by decision of the Chairman of the Committee.

(d) The Control Service invites to the meetings of the Committee any District Administration, Municipality or Local Authority which it considers to be interested in the matters under discussion. Any District Administration, Municipality or Local Authority concerned may send to the meeting an observer who shall have the right to speak but not to vote. Should the service concerned be unable to send an observer, it may send to the Chairman of the Committee written comments on the matter under consideration.

(e) The meetings of the Technical Licensing Committee shall be convened by the Chairman.

(f) Announcements of meetings discussing matters concerning the terms, requirements and conditions for granting authorisation under section 17 shall reach the Ministries involved at least seven (7) days before the date of the meeting.

(g) Minutes of the meetings shall be kept and communicated to the members of the Committee by the Chairman of the Committee.

(h) Committee's operational matters not covered by this Schedule will be dealt with by the Chairman of the Committee.

4. –(a) In case of any disagreement by any member of the Technical Licensing Committee, such member may request the Chairman to record such disagreement in the minutes. If this disagreement concerns the majority of the members of the Committee, then the matter may

be referred to the Minister by If this disagreement concerns the majority of the members of the Committee, then the matter may be referred to the Minister by the Chairman.

Provided that, in this case, the Control Service may draft and send to the Minister, along with the recommendation of the Technical Licensing Committee and the disagreement recorded, its reasoned recommendation, which may be partially or completely different from that of the Committee.

(b) The Minister examines the matter and makes a decision which is final.

## **PART II: Procedures relating for granting authorisation through licensing**

1. All applications for authorisation through licensing, required in accordance with section 8 shall be addressed to the Control Service in forms specified by the Control Service, which shall contain all the information required.

2. Excluding cases of authorisation through licensing for the transport, import, export, shipment or supply of sources or radiation generators or accelerators, before setting, modifying, preparing or making a decision on terms, requirements and conditions in relation to the granting authorisation through licensing, the Control Service consults the Technical Licensing Committee.

3. The Control Service considers the recommendation of the Technical Licensing Committee for the decision on granting authorisation through licensing, but without being bound by it.

4. Subject to the provisions of section 17(5), all decisions concerning applications for authorisation through licensing and its terms, requirements and conditions shall be sent to the applicant by the Control Service.

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## THIRD SCHEDULE

(Sections 12, 16 and 18)

### PART I: Exemption and clearance criteria

#### 1. Exemption

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

#### 2. Exemption and clearance levels

- (a) The total activity values (in Bq) for exemption apply to the total activity involved in a practice and are laid down in column 3 of Part III for artificial radionuclides and for some naturally-occurring radionuclides used in consumer products. For other practices involving naturally-occurring radionuclides, such values are, in general, not applicable.
- (b) The exempt activity concentration values (in kBq kg<sup>-1</sup>) for the materials involved in the practice are laid down in Subpart A of Part II, for artificial radionuclides, and in Subpart B of Part II, for naturally-occurring radionuclides. The values in Subpart A of Part II, are given for individual radionuclides, where applicable, including short-lived radionuclides in equilibrium with the parent nuclide, as indicated. The values in Subpart B of Part II, apply to all radionuclides in the decay chain of U-238 or Th-232, but for segments of the decay chain, which are not in equilibrium with the parent radionuclide, higher values may be applied.

- (c) The concentration values in Subpart A of Part II or in Subpart B of Part II, also apply to the clearance of solid materials for reuse, recycling, conventional disposal or incineration. Higher values may be defined for specific materials or specific pathways, taking European Atomic Energy Community guidance into account, including, where appropriate, additional requirements, in terms of surface activity or monitoring requirements.
- (d) For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate, this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Subpart B of Part II, apply individually to each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of higher values taking European Atomic Energy Community guidance into account.
- (e) The values in Subpart B of Part II, may not be used to exempt the incorporation into building materials of residues from industries processing naturally-occurring radioactive material. For this purpose, compliance with the relevant provisions laid down in the Regulations shall be verified. The values laid down in Part III, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the competent authority may apply these values to smaller entities or packages, for instance to exempt the transport or storage of exempted consumer products, if the general exemption criteria in paragraph (3) are satisfied

### 3. General exemption and clearance criteria

- (a) The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows:
  - (i) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and
  - (ii) the type of practice has been determined to be justified; and
  - (iii) the practice is inherently safe.
- (b) Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Subpart A or Subpart B of Part II are deemed to fulfil criterion of subparagraph (c).

- (c) Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Subpart A or Subpart B of Part II, are deemed to comply with criterion of subparagraph (a) without further consideration. This is also the case for the values in Subpart A of Part II, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water.
- (d) In the case of moderate amounts of material, as specified by Member States for specific types of practice, the activity concentration values laid down in Part III, column 2, may be used instead of the values laid down in Subpart A, Part II, for the purpose of exemption from authorisation.
- (e) For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Subpart A or Subpart B of Part II, an assessment shall be made in the light of the general criteria (i) to (iii) of the subparagraph (a) above. For compliance with the general criterion (i), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:
- (i) For artificial radionuclides:  
The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10  $\mu$ Sv or less in a year.
  - (ii) For naturally-occurring radionuclides:  
The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Competent authority may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

For the purpose of exemption from authorisation, less restrictive dose criteria may be applied.

**PART II: Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material**

Subpart A: Artificial radionuclides

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Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )	Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )	Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )
H-3	100	Co-58	1	Y-93	100
Be-7	10	Co-58m	10 000	Zr-93	10
C-14	1	Co-60	0,1	Zr-95 <sup>α</sup>	1
F-18	10	Co-60m	1000	Zr-97 <sup>α</sup>	10
Na-22	0,1	Co-61	100	Nb-93m	10
Na-24	1	Co-62m	10	Nb-94	0,1
Si-31	1000	Ni-59	100	Nb-95	1
P-32	1000	Ni-63	100	Nb-97 <sup>α</sup>	10
P-33	1000	Ni-65	10	Nb-98	10
S-35	100	Cu-64	100	Mo-90	10
Cl-36	1	Zn-65	0,1	Mo-93	10
Cl-38	10	Zn-69	1000	Mo-99a	10
K-42	100	Zn-69m <sup>α</sup>	10	Mo-101 <sup>α</sup>	10
K-43	10	Ga-72	10	Tc-96	1
Ca-45	100	Ge-71	10000	Tc-96m	1000
Ca-47	10	As-73	1000	Tc-97	10
Sc-46	0,1	As-74	10	Tc-97m	100
Sc-47	100	As-76	10	Tc-99	1
Sc-48	1	As-77	1000	Tc-99m	100
V-48	1	Se-75	1	Ru-97	10
Cr-51	100	Br-82	1	Ru-103 <sup>α</sup>	1
Mn-51	10	Rb-86	100	Ru-105 <sup>α</sup>	10
Mn-52	1	Sr-85	1	Ru-106 <sup>α</sup>	0,1
Mn-52m	10	Sr-85m	100	Rh-103m	10000
Mn-53	100	Sr-87m	100	Rh-105	100
Mn-54	0,1	Sr-89	1000	Pd-103 <sup>α</sup>	1000
Mn-56	10	Sr-90 <sup>α</sup>	1	Pd-109 <sup>α</sup>	100
Fe-52 <sup>α</sup>	10	Sr-91 <sup>α</sup>	10	Ag-105	1
Fe-55	1000	Sr-92	10	Ag-110m <sup>α</sup>	0,1
Fe-59	1	Y-90	1000	Ag-111	100
Co-55	10	Y-91	100	Cd-109 <sup>α</sup>	1
Co-56	0,1	Y-91m	100	Cd-115 <sup>α</sup>	10
Co-57	1	Y-92	100	Cd-115m <sup>α</sup>	100

Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )	Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )	Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )
In-111	10	Cs-132	10	Er-171	100
In-113m	100	Cs-134	0,1	Tm-170	100
In-114m <sup>α</sup>	10	Cs-134m	1000	Tm-171	1000
In-115m	100	Cs-135	100	Yb-175	100
Sn-113 <sup>α</sup>	1	Cs-136	1	Lu-177	100
Sn-125	10	Cs-137 <sup>α</sup>	0,1	Hf-181	1
Sb-122	10	Cs-138	10	Ta-182	0,1
Sb-124	1	Ba-131	10	W-181	10
Sb-125 <sup>α</sup>	0,1	Ba-140	1	W-185	1000
Te-123m	1	La-140	1	W-187	10
Te-125m	1000	Ce-139	1	Re-186	1000
Te-127	1000	Ce-141	100	Re-188	100
Te-127m <sup>α</sup>	10	Ce-143	10	Os-185	1
Te-129	100	Ce-144	10	Os-191	100
Te-129m <sup>α</sup>	10	Pr-142	100	Os-191m	1000
Te-131	100	Pr-143	1000	Os-193	100
Te-131m <sup>α</sup>	10	Nd-147	100	Ir-190	1
Te-132 <sup>α</sup>	1	Nd-149	100	Ir-192	1
Te-133	10	Pm-147	1000	Ir-194	100
Te-133m	10	Pm-149	1000	Pt-191	10
Te-134	10	Sm-151	1000	Pt-193m	1000
I-123	100	Sm-153	100	Pt-197	1000
I-125	100	Eu-152	0,1	Pt-197m	100
I-126	10	Eu-152m	100	Au-198	10
I-129	0,01	Eu-154	0,1	Au-199	100
I-130	10	Eu-155	1	Hg-197	100
I-131	10	Gd-153	10	Hg-197m	100
I-132	10	Gd-159	100	Hg-203	10
I-133	10	Tb-160	1	Tl-200	10
I-134	10	Dy-165	1000	Tl-201	100
I-135	10	Dy-166	100	Tl-202	10
Cs-129	10	Ho-166	100	Tl-204	1
Cs-131	1000	Er-169	1000	Pb-203	10

Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )	Radionuclide	Activity Concentration (kBq·kg <sup>-1</sup> )
Bi-206	1	Pu-244 <sup>α</sup>	0,1
Bi-207	0,1	Am-241	0,1
Po-203	10	Am-242	1000
Po-205	10	Am-242m <sup>α</sup>	0,1
Po-207	10	Am-243 <sup>α</sup>	0,1
At-211	1000	Cm-242	10
Ra-225	10	Cm-243	1
Ra-227	100	Cm-244	1
Th-226	1000	Cm-245	0,1
Th-229	0,1	Cm-246	0,1
Pa-230	10	Cm-247 <sup>α</sup>	0,1
Pa-233	10	Cm-248	0,1
U-230	10	Bk-249	100
U-231 <sup>α</sup>	100	Cf-246	1000
U-232 <sup>α</sup>	0,1	Cf-248	1
U-233	1	Cf-249	0,1
U-236	10	Cf-250	1
U-237	100	Cf-251	0,1
U-239	100	Cf-252	1
U-240 <sup>α</sup>	100	Cf-253	100
Np-237 <sup>α</sup>	1	Cf-254	1
Np-239	100	Es-253	100
Np-240	10	Es-254 <sup>α</sup>	0,1
Pu-234	100	Es-254m <sup>α</sup>	10
Pu-235	100	Fm-254	10000
Pu-236	1	Fm-255	100
Pu-237	100		
Pu-238	0,1		
Pu-239	0,1		
Pu-240	0,1		
Pu-241	10		
Pu-242	0,1		
Pu-243	1000		

(<sup>a</sup>) Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following table:

<b>Parent radionuclide</b>	<b>Progeny</b>
Fe-52	Mn-52m
Zn-69m	Zn-69
Sr-90	Y-90
Sr-91	Y-91m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
Cs-137	Ba-137m
Ce-144	Pr-144, Pr-144m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240m, Np-240
Np-237	Pa-233
Pu-244	U-240, Np-240m, Np-240



Parent radionuclide	Progeny
Am-242m	Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250
Es-254m	Fm-254

For radionuclides not listed in Subpart A of the Part II the Control Service shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Subpart A of the Part II.

#### Subpart B: Naturally occurring radionuclides

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny:

	(kBq·kg <sup>-1</sup> )
Natural radionuclides from the U-238 series	1
Natural radionuclides from the Th-232 series	1
K-40	10

**PART III: Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2)**

Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)
H-3	1 × 10 <sup>6</sup>	1 × 10 <sup>9</sup>	Fe-59	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Be-7	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Co-55	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
C-14	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Co-56	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
O-15	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Co-57	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
F-18	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Co-58	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Na-22	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Co-58m	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Na-24	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Co-60	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Si-31	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Co-60m	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
P-32	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Co-61	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
P-33	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>	Co-62m	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
S-35	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>	Ni-59	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Cl-36	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>	Ni-63	1 × 10 <sup>5</sup>	1 × 10 <sup>8</sup>
Cl-38	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Ni-65	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ar-37	1 × 10 <sup>6</sup>	1 × 10 <sup>8</sup>	Cu-64	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Ar-41	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Zn-65	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
K-40 <sup>α</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Zn-69	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>
K-42	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Zn-69m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
K-43	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ga-72	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Ca-45	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Ge-71	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Ca-47	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	As-73	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Sc-46	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	As-74	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Sc-47	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	As-76	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Sc-48	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	As-77	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
V-48	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Se-75	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Cr-51	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Br-82	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Mn-51	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Kr-74	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>
Mn-52	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Kr-76	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>
Mn-52m	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Kr-77	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>
Mn-53	1 × 10 <sup>4</sup>	1 × 10 <sup>9</sup>	Kr-79	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>
Mn-54	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Kr-81	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Mn-56	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Kr-83m	1 × 10 <sup>5</sup>	1 × 10 <sup>12</sup>
Fe-52	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Kr-85	1 × 10 <sup>5</sup>	1 × 10 <sup>4</sup>
Fe-55	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>	Kr-85m	1 × 10 <sup>3</sup>	1 × 10 <sup>10</sup>

Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)
Kr-87	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Ru-97	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Kr-88	1 × 10 <sup>2</sup>	1 × 10 <sup>9</sup>	Ru-103	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Rb-86	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Ru-105	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Sr-85	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Ru-106 <sup>β</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Sr-85m	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Rh-103m	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Sr-87m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Rh-105	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Sr-89	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Pd-103	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>
Sr-90 <sup>β</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>4</sup>	Pd-109	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Sr-91	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Ag-105	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Sr-92	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ag-108m	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Y-90	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Ag-110m	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Y-91	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Ag-111	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Y-91m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Cd-109	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>
Y-92	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Cd-115	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Y-93	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Cd-115m	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Zr-93 <sup>β</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	In-111	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Zr-95	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	In-113m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Zr-97 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	In-114m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Nb-93m	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	In-115m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Nb-94	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Sn-113	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Nb-95	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Sn-125	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Nb-97	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Sb-122	1 × 10 <sup>2</sup>	1 × 10 <sup>4</sup>
Nb-98	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Sb-124	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Mo-90	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Sb-125	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Mo-93	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>	Te-123m	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Mo-99	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Te-125m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Mo-101	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Te-127	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Tc-96	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Te-127m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Tc-96m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Te-129	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Tc-97	1 × 10 <sup>3</sup>	1 × 10 <sup>8</sup>	Te-129m	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Tc-97m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Te-131	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Tc-99	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Te-131m	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Tc-99m	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Te-132	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>

Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)
Te-133	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Pr-143	1 × 10 <sup>4</sup>	1 × 10 <sup>6</sup>
Te-133m	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Nd-147	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Te-134	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Nd-149	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
I-123	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Pm-147	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
I-125	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Pm-149	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
I-126	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Sm-151	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
I-129	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Sm-153	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
I-130	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Eu-152	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
I-131	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Eu-152m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
I-132	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Eu-154	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
I-133	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Eu-155	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
I-134	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Gd-153	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
I-135	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Gd-159	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Xe-131m	1 × 10 <sup>4</sup>	1 × 10 <sup>4</sup>	Tb-160	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Xe-133	1 × 10 <sup>3</sup>	1 × 10 <sup>4</sup>	Dy-165	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Xe-135	1 × 10 <sup>3</sup>	1 × 10 <sup>10</sup>	Dy-166	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Cs-129	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Ho-166	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>
Cs-131	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Er-169	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Cs-132	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Er-171	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Cs-134m	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>	Tm-170	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Cs-134	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Tm-171	1 × 10 <sup>4</sup>	1 × 10 <sup>8</sup>
Cs-135	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Yb-175	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Cs-136	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Lu-177	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Cs-137 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Hf-181	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Cs-138	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Ta-182	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Ba-131	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	W-181	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Ba-140 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	W-185	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
La-140	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	W-187	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Ce-139	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Re-186	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Ce-141	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Re-188	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Ce-143	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Os-185	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Ce-144 <sup>β</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Os-191	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Pr-142	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Os-191m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>

Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)	Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)
Os-193	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Ra-225	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Ir-190	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Ra-226 <sup>b</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Ir-192	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Ra-227	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Ir-194	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Ra-228 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Pt-191	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Ac-228	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Pt-193m	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Th-226 <sup>β</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Pt-197	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	Th-227	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Pt-197m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Th-228 <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Au-198	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Th-229 <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Au-199	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Th-230	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Hg-197	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>	Th-231	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Hg-197m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Th-234 <sup>β</sup>	1 × 10 <sup>3</sup>	1 × 10 <sup>5</sup>
Hg-203	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Pa-230	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Tl-200	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	Pa-231	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Tl-201	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	Pa-233	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Tl-202	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	U-230	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>
Tl-204	1 × 10 <sup>4</sup>	1 × 10 <sup>4</sup>	U-231	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Pb-203	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>	U-232 <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Pb-210 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	U-233	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Pb-212 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	U-234	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Bi-206	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	U-235 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Bi-207	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-236	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Bi-210	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>	U-237	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Bi-212 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	U-238 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Po-203	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-239	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Po-205	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-240	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Po-207	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>	U-240 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Po-210	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>	Np-237 <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
At-211	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>	Np-239	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Rn-220 <sup>β</sup>	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>	Np-240	1 × 10 <sup>1</sup>	1 × 10 <sup>6</sup>
Rn-222 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>8</sup>	Pu-234	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Ra-223 <sup>β</sup>	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>	Pu-235	1 × 10 <sup>2</sup>	1 × 10 <sup>7</sup>
Ra-224 <sup>β</sup>	1 × 10 <sup>1</sup>	1 × 10 <sup>5</sup>	Pu-236	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>

Radionuclide	Activity concentration (kBq·kg <sup>-1</sup> )	Activity (Bq)
Pu-237	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Pu-238	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Pu-239	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Pu-240	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Pu-241	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Pu-242	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Pu-243	1 × 10 <sup>3</sup>	1 × 10 <sup>7</sup>
Pu-244	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Am-241	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Am-242	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Am-242m <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Am-243 <sup>β</sup>	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Cm-242	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Cm-243	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Cm-244	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Cm-245	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Cm-246	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Cm-247	1 × 10 <sup>0</sup>	1 × 10 <sup>4</sup>
Cm-248	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Bk-249	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Cf-246	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>
Cf-248	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Cf-249	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Cf-250	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Cf-251	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Cf-252	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Cf-253	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Cf-254	1 × 10 <sup>0</sup>	1 × 10 <sup>3</sup>
Es-253	1 × 10 <sup>2</sup>	1 × 10 <sup>5</sup>
Es-254	1 × 10 <sup>1</sup>	1 × 10 <sup>4</sup>
Es-254m	1 × 10 <sup>2</sup>	1 × 10 <sup>6</sup>
Fm-254	1 × 10 <sup>4</sup>	1 × 10 <sup>7</sup>
Fm-255	1 × 10 <sup>3</sup>	1 × 10 <sup>6</sup>

(a) Potassium salts in quantities less than 1000 kg are exempted.

(b) Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered), are listed in the following:

Parent radionuclide	Progeny
Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0,36), Po-212 (0,64)
Bi-212	Tl-208 (0,36), Po-212 (0,64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0,36), Po-212 (0,64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0,36), Po-212 (0,64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0,36), Po-212 (0,64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

## FOURTH SCHEDULE

(Section 17)

### Indicative list of information for authorisations through licensing applications

- (a) Responsibilities and organisational arrangements for safety, security and protection against ionising radiation.
- (b) Personnel skills, including information, education and training received.
- (c) Design and location characteristics of the installation and radiation sources.
- (d) Expected occupational and public exposures in normal operating conditions.
- (e) Safety assessments of practices, activities and facilities so that to:
  - (i) identify ways in which potential exposures or accidental exposures and unintentional medical exposures may happen;
  - (ii) assess as far as practicable the likelihood and magnitude of potential exposures;
  - (iii) evaluate the quality and extent of the security and safety measures envisaged, including technical characteristics and administrative procedures;
  - (iv) specify the operating limits and operating conditions.

Provided that, the requirements of this element may be satisfied by the submission of the safety assessment referred to in the Seventh Schedule.

- (f) Emergency procedures.
  - (g) Maintenance, testing, inspection and regular control to ensure that the radiation sources and installation continue to meet the design requirements, operating limits and operating conditions throughout their operational life.
  - (h) Management of radioactive waste and disposal measures in accordance with applicable regulatory requirements.
  - (i) Management of disused sources.
  - (j) Quality assurance.
  - (k) General undertaking information (e.g. undertaking name as it is registered in the Department of Registrar of Companies and Official Receiver, address, undertaking details etc.)
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**FIFTH SCHEDULE**

(Section 19)

**List of industrial sectors involving naturally-occurring radioactive materials**

When applying section 19 the following list of industrial sectors involving naturally-occurring radioactive material, including research and relevant secondary processes, shall be taken into account:

- (a) Extraction of rare earths from monazite.
  - (b) Production of thorium compounds and manufacture of thorium-containing products.
  - (c) Processing of niobium/tantalum ore.
  - (d) Oil and gas production.
  - (e) Geothermal energy production.
  - (f) TiO<sub>2</sub> pigment production.
  - (g) Thermal phosphorus production.
  - (h) Zircon and zirconium industry.
  - (i) Production of phosphate fertilisers.
  - (j) Cement production, maintenance of clinker ovens.
  - (k) Coal-fired power plants, maintenance of boilers.
  - (l) Phosphoric acid production.
  - (m) Primary iron production.
  - (n) Tin/lead/copper smelting.
  - (o) Ground water filtration facilities.
  - (p) Mining of ores other than uranium ore.
-

## SIXTH SCHEDULE

(Section 33)

### **List of items to be considered during review and assessment of information relevant to safety, security and protection from ionising radiation**

When examining and evaluating information related to safety, security and protection against ionising radiation in respect of an installation, practice or activity of an undertaking, the Control Service takes into account, in accordance with the graded approach, the indicative information of the following non-exhaustive list:

- (a) The regulatory requirements.
- (b) Responsibilities and organisational arrangements for safety, security and protection against ionising radiation.
- (c) The nature and categorisation of associated risks.
- (d) The conditions prevailing in the installation and the operating environment of the installation.
- (e) The basic design of the installation or the pursuit of a practice or activity, in relation to safety, security and radiation protection.
- (f) The records provided by the undertaking or its suppliers.
- (g) Best practices.
- (h) The current management system.
- (i) The competence and skills necessary for the operation of the installation or the conduct of the practice or activity.
- (j) The arrangements for the protection of workers, the public, patients and the environment.
- (k) The arrangements for emergency preparedness and response.
- (l) Arrangements for nuclear or radiological protection.
- (m) The system of accounting and control of nuclear material.
- (n) The relevance of the application of the principle of defense in depth in order to take into account inherent uncertainties (e.g. long-term for the disposal of radioactive waste).
- (o) The arrangements for the management of radioactive sources, radioactive waste and spent fuel.

- (p) The relevant research and development programme or programmes on the demonstration of safety and security.
  - (q) Feedback from operational experience, at national and international level, and in particular the relevant operational experience from similar installations and practices or activities.
  - (r) The information gathered during inspections of the Control Service.
    - (a) The information from findings in research.
    - (b) The shutting down arrangements.
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**SEVENTH SCHEDULE**

(Section 45)

**PART I: List of items to be included in the safety assessment**

- (a) Name and address of the applicant, undertaking or carrier.
- (b) Postal address of premises or installations where the relevant activities are conducted or the undertaking to conduct the transfer.
- (c) Date of commencement of activities.
- (d) General description of premises or installations, including geographical location, meteorological, geological and hydrographic conditions, and in the case of transport:
  - (i) the starting and ending point of the transport and the intermediate transit points; or
  - (ii) the route selection criteria.
- (e) Description of radioactive substances and their quantities.
- (f) Plans of premises or installations.
- (g) Diagram and description of any equipment containing radioactive substances and a description of the packaging or inclusion of the radioactive substance, vehicle and means of retaining the substance on or inside the vehicle.
- (h) Description of all factors which may result in the continuous release of radioactive substances into the environment and measures to prevent or control them.
- (i) Information on the undertaking's management and staff.
- (j) Information on the size and distribution of the population around the premises or installations to which the safety assessment relates.
- (k) Assessment of the area that may be affected by the dispersion of radioactive substances and the time that such dispersion can last.
- (l) Assessment of the radiation doses to which any person or group of persons can be exposed.
- (m) Assessment of whether it is necessary to prepare an emergency plan.

**PART II: Additional information to be included in the safety assessment upon request of the Control Service**

- (a) Analysis to determine the consequences of any risk, including doses to which the population may be exposed, as well as the chances of this happening.
- (b) The number of persons who may be affected.
- (c) The management system and the staff which implement or will implement measures to protect against the risks identified.
- (d) Safety systems, methods and monitoring and recording systems for risk control.
- (e) The qualifications, experience and training of staff.
- (f) The design, construction, operation and maintenance of equipment used for intervention or risk control purposes.
- (g) The design and operation manuals.
- (h) The measures to protect any person in the event that the intervention measures prove insufficient.
- (i) The procedures for notification of radiation emergency and drawing conclusions and lessons.

**PART III: Principles to be considered in the preparation of an emergency response plan**

- (a) Any intervention will be undertaken only if the reduction of the catastrophic effects due to a radiological emergency is of such magnitude as to justify the damage and costs, including the social costs, to be caused by the intervention; and
- (b) The type, extent and duration of the operation must be such as to ensure that radiation exposure is kept at the lowest possible level, resulting in the benefit of reducing the damage to health, after subtracting the damage that may be caused by the intervention, is maximised.

**PART IV**

**Subpart A: Minimum information to be included in an internal emergency response plan**

- (a) The names and positions of the persons authorised to sound an alarm and to implement the internal emergency response plan and the person responsible for

coordinating actions to deal with the consequences within the premises or installations.

- (b) The name and location of the person acting as a liaison officer with the Control Service, the Local Authorities and other Agencies and Organizations involved.
- (c) Situations or events which may lead to radiation emergencies and a description of the actions to be taken and the measures to be taken to mitigate the consequences, including information on the available safety equipment and other available means and personnel.
- (d) Arrangements to reduce the risks to persons in premises or installations, including the way in which they are alerted and the actions to which such persons are expected to take.
- (e) The arrangements for the timely notification of the Control Services responsible for implementing the national emergency response plan, the type of information to be contained in the initial notification and the arrangements for providing additional information when newer data are available.
- (f) Arrangements for assistance by actions outside premises or installations.
- (g) Arrangements for emergency response reports and dose levels established as appropriate for the purpose of initiating the implementation of the internal emergency response plan.

Subpart B: Minimum information to be included in an internal emergency response plan during transport

- (a) The names and locations of persons authorised to sound an alarm and to implement the internal transport emergency response plan and the person responsible for coordinating actions to deal with the consequences.
- (b) Situations or events which may lead to radiation emergencies and a description of the actions to be taken and the measures to be taken to mitigate the consequences, including information on the available safety equipment and other available means and personnel.
- (c) The arrangements for early notification of the event, the type of information to be contained in the initial notification and the arrangements for providing additional information when newer data is available.

- (d) The arrangements for emergency response reports, as well as the dose levels established as appropriate for the purpose of initiating implementation of the internal transport emergency response plan.
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## **EIGHTH SCHEDULE**

(Sections 53 and 54)

### **Emergency management systems and emergency response plans**

#### **PART I: Elements to be included in an emergency management system.**

- (a) Assessment of potential emergency exposure situations and associated public, occupational and emergency occupational exposures.
- (b) Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements.
- (c) Establishment of emergency response plans at appropriate levels and related to a specific facility or human activity.
- (d) Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and at appropriate national and international levels.
- (e) Health protection of emergency workers.
- (f) Arrangements for the provision of prior information and training for emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises.
- (g) Arrangements for individual monitoring or assessment of individual doses of emergency workers and the recording of doses.
- (h) Public information arrangements.
- (i) Involvement of stakeholders.
- (j) Transition from an emergency exposure situation to an existing exposure situation including recovery and remediation.

#### **PART II: Elements to be included in an emergency response plan**

##### Elements to be included in an emergency response plan:

- (a) Reference levels for public exposure, taking into account the criteria laid down in Regulations issued pursuant to this Law.



- (b) Reference levels for emergency occupational exposure taking into account the Regulations, concerning the emergency occupational exposure, issued pursuant to this Law.
- (c) Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios.
- (d) Predefined generic criteria for particular protective measures.
- (e) Default triggers or operational criteria such as observables and indicators of on-scene conditions.
- (f) Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other EURATOM Member States and with third countries which may be involved or are likely to be affected.
- (g) Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

For emergency response:

The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:

- (a) Promptly implementing protective measures, if possible, before any exposure occurs.
- (b) Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation.
- (c) Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level.
- (d) Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

**NINTH SCHEDULE**

(Section 57)

**Indicative list of types of existing exposure situations**

- (a) Exposure due to contamination of areas by residual radioactive material from:
    - (i) past activities that were never subject to regulatory control or were not regulated;
    - (ii) a radiation emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;
    - (iii) residues from past activities for which the undertaking is no longer legally accountable.
  - (b) Exposure to natural radiation sources, including:
    - (i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings;
    - (ii) indoor external exposure from building materials.
  - (c) Exposure to commodities excluding food, animal feeding stuffs and drinking water incorporating:
    - (i) radionuclides from contaminated areas specified in point (a), or
    - (ii) naturally-occurring radionuclides.
-

**TENTH SCHEDULE**

(Section 60)

**List of items to be considered in preparing the national action plan to address long-term risks from radon exposures**

- (a) Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and Radium-226 content of rock or soil).
- (b) Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.
- (c) Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a risk assessment, considering for instance occupancy hours.
- (d) The basis for the establishment of reference levels for dwellings and workplaces. If applicable, the basis for the establishment of different reference levels for different uses of buildings (dwellings, buildings with public access, workplaces) as well as for existing and for new buildings.
- (e) Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.
- (f) Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under point (b).
- (g) Strategies for facilitating post construction remedial action.
- (h) Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.
- (i) Schedules for reviews of the action plan.
- (j) Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking.

- (k) Guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.
  - (l) Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.
  - (m) Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non- smokers).
  - (n) Where appropriate, consideration of other related issues and corresponding programmes such as programmes on energy saving and indoor air quality.
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**ELEVENTH SCHEDULE**

(Section 62)

**Subjects to be provided by the Regulations issued in accordance to section 62**

Regulations issued pursuant to section 62 may provide for or have the following purposes as those laid down in:

- (a) Regulate notifications, authorisations or exclusions of practices or sources as well as radiological or nuclear safety, security and radiation protection requirements.
- (b) Regulate the import, export, shipment, transport, storage, discharge or disposal of radiation sources in the Republic.
- (c) Determine the exposures to ionising radiation which are excluded from the application of any provisions of this Law.
- (d) Determine the obligations, including financial terms and conditions of financial security, which may be imposed on those who possess radiation sources or conduct practices where radiation is used.
- (e) Regulate the conduct of inspections of sources, practices and facilities and measures for the purposes of applying the terms, requirements and conditions of authorisation or applicable legislation.
- (f) Regulate the determination of fees for granting authorisation or the provision of any other service under this Law.
- (g) Regulate the prevention and response to radiation emergencies and radiological accidents.
- (h) Regulate intervention in cases of chronic exposure.
- (i) Regulate the information of the public or research conduct in relation to radiation.
- (j) Regulate the medical supervision of persons exposed to ionising radiation.
- (k) Regulate occupational exposure, public exposure and medical exposure.
- (l) Regulate the investigation of accidents and dangerous incidents.
- (m) Regulate research and development in matters related to the use of ionising radiation or the application of nuclear techniques.
- (n) Regulate issues related to monitoring levels of radioactivity in environmental receptors and products or other goods.

- (o) Regulate issues related to nuclear or radiological safety and/or radioactive waste management.
  - (p) Regulate issues of surveillance and control of shipments of radioactive waste and spent nuclear fuel.
  - (q) Regulate issues concerning the protection of the population from radioactive substances contained in goods intended for human consumption.
  - (r) Regulate issues related to the control of closed high-activity radioactive sources.
  - (s) Regulate issues of safeguarding nuclear material.
  - (t) Regulate issues of security of nuclear or radioactive materials.
  - (u) Set the basic safety standards and radiation protection.
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