STATUTORY INSTRUMENTS.

S.I. No. 30 of 2019

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RADIOLOGICAL PROTECTION ACT 1991 (IONISING RADIATION) REGULATIONS 2019

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ARRANGEMENT OF REGULATIONS

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RADIOLOGICAL PROTECTION ACT 1991 (IONISING RADIATION) REGULATIONS 2019

I, RICHARD BRUTON, Minister for Communications, Climate Action and Environment, in exercise of the powers conferred on me by subsections (1) and (2) of Section 30 of the Radiological Protection Act 1991 (No. 9 of 1991), after consultation with the Ministers for Public Expenditure and Reform, Health, Housing, Planning and Local Government, and the Environmental Protection Agency, Health Information and Quality Authority, and the Health and Safety Authority for the purpose of giving effect to Council Directive 2013/59/EURATOM of 5 December 2013[1], as affected by Corrigendum to Council Directive 2013/59/EURATOM[2], laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and for the purpose of giving further effect to Council Directive 2011/70/EURATOM of 19 July 2011[3] establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, hereby make the following Regulations: –

Part 1 - CITATIONS, DEFINITIONS AND SCOPE

Citation

1. These Regulations may be cited as the Radiological Protection Act 1991 (Ionising Radiation) Regulations 2019.

Definitions

2. (1) In these Regulations: –

"Absorbed dose" (D) is 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;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil 8*th of February*, 2019.

[1] OJ No. L.13, 17.01.2014, p.1.
[2] OJ No. L.72, 17.03.2016, p.69.
[3] OJ L 199, 2.8.2011, p. 48–56

dm is the mass of the matter in this volume element.

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

$1\,\mathrm{Gy} = 1\,\mathrm{J\,kg^{-1}}$;

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

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

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

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

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

The unit of activity is the becquerel (Bq);

"air crew" means the cabin and flight crew of an aircraft operated by an air operator or an undertaking in the State which operates an aircraft;

"air operator" means the holder of an Air Operator's Certificate issued by the Irish Aviation Authority in accordance with the Irish Aviation Authority (Air Operators' Certificate) Order 1999 (S.I. No. 420 of 1999);

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

"approved 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 Agency;

"authorisation" means the registration or licensing of a practice;

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

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

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

"category A worker" means an exposed worker designated as such pursuant to Regulation 39;

"category B worker" means an exposed worker designated as such pursuant to Regulation 39;

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

"closure" means the completion of all operations at some time after the emplacement of radioactive waste in a disposal facility, including the final engineering or other work required to bring the facility to a condition that will be safe in the long term;

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

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

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

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

It is given by: –

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

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*,

τ is the time over which the integration is performed.

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

"competent authority" means the Environmental Protection Agency ("the Agency") established under Section 19 of the Environmental Protection Agency Act 1992 (No. 7 of 1992);

"Competition and Consumer Protection Commission" means the body established under section 9 of the Competition and Consumer Protection Act 2014;

"Community" means the European Atomic Energy Community;

"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;

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

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

"Council Directive" means 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, as affected by Corrigendum to Council Directive 2013/59/EURATOM, and repealing Directives 89/618/EURATOM, 90/641/EURATOM, 96/29/EURATOM, 97/43/EURATOM and 2003/122/EURATOM;

"disposal" means, in relation to radioactive waste, the emplacement of waste in a repository, or a given location, without the intention of retrieval;

"disposal facility" means any facility or installation the primary purpose of which is radioactive waste disposal;

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

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

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

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

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

Where

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

The values for w_T and w_R are specified in Schedule 2. The unit for effective dose is the sievert (Sv);

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

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

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

"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;

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

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

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

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

where

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

w_R is the radiation weighting factor.

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

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

The values for w_R are specified in Schedule 2, Part A. The unit for equivalent dose is the sievert (Sv);

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

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

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

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

"exposure to radon" means exposure to radon progeny;

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

"high-activity sealed source" means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the corresponding activity value laid down in Schedule 3;

“high radon area” means an area where the Agency predicts that more than 10% of domestic dwellings in that area will have radon concentrations above the national reference level or such other area as the Agency may determine from time to time;

“inspection” means an investigation by or on behalf of the Agency to verify compliance with national legal requirements;

“inspector” means a person appointed under Section 28 of the Principal Act to be an inspector for the purposes of that Act and orders or regulations made under it;

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

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

“irradiating apparatus” means an electrical apparatus capable of producing ionising radiation and containing components operating at a potential difference of more than 5kV;

“licence” means permission granted in a document by the Agency to carry out a practice in accordance with specific conditions (if any) laid down in that document;

“local authority” has the meaning given to it in the Local Government Act 2001;

“local government area” shall be read in accordance with section 10 of the Local Government Act 2001;

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

“medical physics expert” has the meaning given to it in Regulation 2(1) of the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018);

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

“Member State” means a Member State of the European Union;

“Minister” means the Minister for Communications, Climate Action and Environment;

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

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

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

"notification" means submission of information to the Agency to notify the intention to carry out a practice within the scope of these Regulations;

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

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

"orphan source" means a radioactive source which is neither exempted nor under regulatory control, for example because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation;

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

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

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

"practice" means a relevant activity that is managed as a planned exposure situation;

"practitioner" has the meaning given to it in Regulation 2(1) of the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018);

"Principal Act" means the Radiological Protection Act 1991 (No. 9 of 1991);

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

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

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

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

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

"radiation generator" means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles including irradiating apparatus and nuclear generators;

"radiation passbook" means: –

(a) in the case of an outside worker a passbook approved for the purposes of these Regulations by the Agency in accordance with the requirements of Schedule 9;

(b) in the case of an outside worker employed in another Member State, a passbook authorised by a competent authority of that Member State; and

(c) in the case of an outside worker employed in a third country, a passbook authorised by a competent authority of that country;

"radiation protection adviser" means an individual or a body, having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, which meets such criteria of competence as may from time to time be specified in writing by the Agency;

“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;

“radiation source” means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material and encompasses radiation generator, radioactive material, radioactive source and radioactive substance;

“radioactive material” means material incorporating radioactive substances;

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

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

“radioactive waste” means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Agency or by a legal or natural person whose decision is accepted by the Agency, and which is regulated as radioactive waste by the Agency;

“radioactive waste management” means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation;

“radioactive waste management facility” means any facility or installation the primary purpose of which is radioactive waste management;

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

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

“registration” means permission granted in a document by the Agency, to carry out a practice in accordance with attached conditions (if any) for this type or class of practice;

“registered person” means a person to whom a registration is for the time being granted;

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

"relevant activity" means a human activity which can increase the exposure of individuals to radiation from a radiation source and includes the custody, production, processing, handling, holding, storage, use, recycling, manufacture, import, distribution, transport, export or other disposal of the radiation source;

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

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

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

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

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

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

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

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

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[4] Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures, 2010.
[5] Compendium of Dose Coefficients based on ICRP Publication 60, 2012.

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

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

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

"Waste Directive" means Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste;

"workplace" includes any place, land or other location at, in, upon or near which, work is carried out whether occasionally or otherwise and, in particular, includes: –

(a) a premises, including a cave or mine;

(b) an installation on land and any offshore installation;

(c) a tent, a temporary structure or movable structure; and

(d) a vehicle, vessel, aircraft or spacecraft.

(2) A word or expression which is used in these Regulations and which is also used in the Council Directive or the Waste Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Council Directive or the Waste Directive.

(3) In these Regulations: –

(a) a reference to a Regulation or Schedule is a reference to a Regulation of or Schedule to these Regulations unless it is indicated that a reference to some other enactment is intended; and

(b) a reference to a paragraph, subparagraph or clause is a reference to a paragraph, subparagraph or clause of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended.

Scope

3. These Regulations apply to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be

disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection including: –

(a) the custody, manufacture, operation, production, processing, handling, use, storage, holding, transport, distribution, recycling or disposal, import, and export of radiation sources;

(b) in relation to the use of radiation sources as a prophylactic, diagnostic or therapeutic agent for the purpose of the prevention, diagnosis or treatment of any human ailment, infirmity, injury or defect, the scope is limited to: –

(i) the supervision and care of the radiation sources; and

(ii) ensuring that the said radiation sources are properly calibrated and maintained so as: –

(I) to reduce to a minimum the effects of such radiation sources on property and persons other than a patient receiving a particular medical or dental application; and

(II) to enable a practitioner to achieve the maximum degree of accuracy and safety where the said radiation sources are used for the benefit of an individual patient.

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

(i) the operation of aircraft and spacecraft, in relation to the exposure of crews; and
(ii) the processing of materials with naturally-occurring radionuclides.

(d) the exposure of workers or members of the public to radon in buildings and external exposure from building materials;

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

(f) all stages of radioactive waste management, from generation to disposal, when the radioactive waste results from civilian activities;

(g) cases of lasting exposure resulting from the after-effects of an emergency or a past human activity; and

(h) any other practice specified by the Agency.

Exclusion from Scope

4. These Regulations do 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 spacecrew to cosmic radiation in flight or in space; and

(c) above ground exposure to radionuclides present in the undisturbed earth's crust.

Part 2 - REGULATORY CONTROL

Section 1 - Justification

Justification of practices

5. (1) No practice shall be authorised under these Regulations unless it falls within a class or type of practice that is: –

(a) carried out immediately before the commencement of these Regulations; or

(b) justified by the Agency in regards to its economic, social, health, environmental or other benefits in relation to the detriment it may cause; or

(c) justified by the Health Information and Quality Authority in regards to medical exposures in accordance with Regulation 7 of the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018).

(2) The Agency shall consult with the Minister before justifying a class or type of practice in accordance with subparagraph (1)(b).

(3) The Agency may, before justifying a class or type of practice in accordance with subparagraph (1)(b), or for the purposes of a review under paragraph (4), consult with: –

(a) such Ministers of the Government (if any) as it considers appropriate;

(b) occupational health services;

(c) professional bodies of practitioners;

(d) Health Information and Quality Authority;

(e) Health Service Executive;

(f) Health and Safety Authority;

(g) Food Safety Authority of Ireland; or

(h) such other persons or bodies as the Minister may direct.

(4) Classes or types of practice carried out or justified in accordance with paragraph (1) may be reviewed by the Agency periodically with regard to their justification, including whenever there is new and important evidence about their efficacy or potential consequences, or new and important information about other techniques and technologies.

(5) If following such a review, a class or type of practice is deemed to be no longer justified, the Agency shall withdraw or revoke such registrations or licences, as the case may be, for the carrying out of such practices, pursuant to its powers under Section 30(5) of the Principal Act.

(6) The Agency may publish a list of practices deemed to be justified and/or not justified, including whether particular applications of a practice fall within an accepted class or type of practice.

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

(8) Each particular application of a generally accepted type of practice involving non-medical imaging exposure shall be justified by the Agency.

(9) All individual non-medical imaging exposure procedures using medical radiological equipment shall be justified by a practitioner in advance, taking into account the specific objectives of the procedure and the characteristics of the individual involved.

Practices involving consumer products

6. (1) Any undertaking intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, shall provide the Agency with all relevant information including that listed in Schedule 4, Part A so as to allow the implementation of the justification requirement in Regulation 5.

(2) The Agency shall decide whether the intended use of the consumer product is justified taking into account, *inter alia*: –

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

(b) the design is adequate in order to: –

(i) minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there should be conditions imposed on the technical and physical characteristics of the product;

(ii) meet the exemption criteria;

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

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

(3) Without prejudice to paragraph (1), the Agency, as the competent authority which has received information according to that paragraph, shall inform the point of contact for the competent authorities of other Member States of this receipt and, upon request, of its decision and the basis for that decision.

(4) The Agency shall notify the Competition and Consumer Protection Commission if the intended use of a consumer product is not justified or its use would not fulfil the criteria for exemption from notification under Regulation 9.

Prohibition of practices

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

(2) The deliberate addition of radioactive substances in the manufacture of toys and personal ornaments is also prohibited, as is the import or export of such products.

(3) Without prejudice to the Directive 1999/2/EC [6]of the European Parliament and of the Council practices involving the activation of material resulting in an increase in activity in a consumer product, which at the time of placing on the market cannot be disregarded from a radiation protection point of view, shall be deemed not to be

[6] OJ L 66, 13.3.1999, p. 16–23

justified. However, the Agency may evaluate specific types of practices within this class with regard to their justification.

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

Section 2 – Graded Approach to Authorisation

Notification

8. (1) Undertakings shall notify the Agency before commencing any justified practice including those identified in Regulation 68, which has not been previously exempted by the Agency from the requirement for notification in accordance with Regulation 9.

(2) Notification to the Agency shall be required in respect of radon in workplaces as specified in Regulation 66, and for existing exposure situations that are managed as a planned exposure situation as provided for in Parts 7 and 8 of these Regulations.

(3) Notwithstanding the exemption criteria laid down in Regulation 9, in situations identified by the Agency where there is concern that a practice identified in accordance with Regulation 68 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the Agency may require that the practice be subject to notification. This is without prejudice to the provisions of the European Union (Radioactive Substances in Drinking Water) Regulations 2016 (S.I. No. 160 of 2016).

(4) Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with Regulation 19 shall not be managed as a planned exposure situation and, hence, are not required to be notified.

(5) A separate notification will not be necessary where an application for authorisation is submitted to the Agency.

(6) The Agency shall produce guidelines specifying the information to be provided in the notification process.

(7) (a) Without prejudice to Regulations 10 and 11, where appropriate, the Agency may exempt notified practices from the requirement for registration or licensing on the basis of the general criteria specified in Schedule 7;

(b) In the case of moderate amounts of material, as specified by the Agency for specific types of practice, the activity concentration values laid down in Schedule 7, Table B, column 2, may be used instead of the values laid down in Schedule 7, Table A, Part 1, for the purpose of exemption from authorisation.

Exemption from Notification

9. (1) The Agency may exempt justified practices, involving the following, from notification requirements: –

(a) radioactive materials where the quantities of the activity involved do not exceed in total the exemption values set out in Column 3, Table B of Schedule 7, or higher values that, for specific applications, are approved by the Agency and satisfy the general exemption and clearance criteria set out in Schedule 7;

(b) without prejudice to Regulation 8(4), radioactive materials where the activity concentrations do not exceed the exemption values set out in Table A of Schedule 7, or higher values that, for specific applications, are approved by the Agency and satisfy the general exemption criteria set out in Schedule 7;

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

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

(ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding $1\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface; and

(iii) conditions for recycling or disposal have been specified by the Agency; 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 Agency; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding $1\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface.

(2) The Agency may exempt specific types of practices from the notification requirement subject to compliance with the general exemption criteria established in Part 3 of Schedule 7, on the basis of an assessment showing that exemption is the best option.

Registration or licensing

10. (1) The Agency shall require either registration or licensing of the following practices: –

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

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

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

(3) Subject to Regulation 11, the Agency shall, in accordance with paragraphs (1) and (2), determine which practices are subject to registration or licensing. The Agency shall base its decision to submit a type of practice to registration or licensing on regulatory experience taking into account: –

(a) the magnitude of expected or potential doses resulting from the practice;

(b) the impact that regulatory control may have in reducing such doses or improving radiological safety;

(c) the complexity of the practice; and

(d) safety, security and any safeguards required having regard to the circumstances in which the relevant practice is proposed to be carried out.

Licensing

11. (1) Licensing shall be required for the following practices: –

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

(b) the operation and decommissioning of any nuclear facility 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 medical products, and the import of such products;

(d) any practice involving a high-activity sealed source;

(e) the siting, design, construction, commissioning, operation, decommissioning and closure of a radioactive waste management facility;

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

(g) the exportation for disposal of radioactive waste from the State to another Member State or third country, or the importation for disposal in the State of radioactive waste generated in another Member State or third country.

Authorisation

12. (1) The Agency shall establish and maintain: –

(a) a register of registered practices; and

(b) a register of licensed practices.

(2) Where the Agency grants or amends authorisation of a practice, it shall enter in the appropriate register referred to in paragraph (1) particulars of: –

(a) the practice registered or licensed, as the case may be;

(b) the registered person or licensee, as the case may be;

(c) the purpose for which the practice has been registered or licensed;

(d) any conditions attached by the Agency to the registration or specified in the licence; and

(e) such other particulars as the Agency considers appropriate.

(3) A practice for which a licence or registration is granted by the Agency in accordance with paragraph (2), may be carried out in accordance with the registration or licence, as the case may be, from the date on which the particulars referred to in that subsection are entered in the register of registered practices or the register of licensed practices, as appropriate.

(4) When a licence has been granted, no modifications to equipment or facilities, subject of that licence, shall be carried out without the prior consent of the Agency.

(5) Practices shall not be carried out unless authorised by the Agency or exempted from the requirement for authorisation under Regulation 8(7).

Authorisation procedure

13. An application for an authorisation shall be in such form and include such information as may be set out in Regulations made by the Minister under Section 30(7) of the Principal Act.

Conditions specified in a Licence

14. (1) The Agency may specify conditions in a licence.

(2) In determining the conditions to be specified in a licence, the Agency shall have regard to: –

(a) the nature of the practice and the circumstances in which it is carried out, including any equipment used in carrying it out;

(b) the nature of the radiation source to which the practice relates;

(c) the levels of exposure from the radiation source to which the practice relates; and

(d) any particular safety and security measures and safeguards that may be required for the purpose of the practice being safely and securely carried out, having regard to the circumstances in which the practice is carried out.

(3) The Agency shall, where applicable, specify conditions: –

(a) requiring the formal and documented implementation of the principle of optimisation; and

(b) on the discharge of radioactive effluent in accordance with plans approved and limits established under Regulation 51.

(4) Conditions specified in a licence by the Agency under this Regulation may include a condition that the licence shall be revoked where the Agency is of the opinion that any of those conditions has not been complied with.

(5) The Agency may amend, including by specifying new conditions or the amendment of a practice stated to be registered, or revoke a licence.

(6) Where the Agency has specified a condition in a licence, the undertaking shall comply with that condition.

(7) A licence shall not be transferred.

Conditions attached to a Registration

15. (1) The Agency may attach to a registration conditions which the Agency considers are appropriate to be applied generally to the registration of the practice concerned having regard to the manner in which that practice is carried out by members of the profession of which the applicant for authorisation is a member or having regard to the manner in which that practice is usually carried out by a person who is, in the opinion of the Agency, substantially similar to the applicant.

(2) In determining the conditions to be attached to a registration, the Agency shall have regard to: –

(a) the nature of the practice and the circumstances in which it is carried out, including any equipment used in carrying it out;

(b) the nature of the radiation source to which the practice relates; and

(c) the levels of exposure from the radiation source to which the practice relates.

(3) Conditions attached to a registration by the Agency under this Regulation may include a condition that the registration shall be withdrawn where the Agency is of the opinion that any of those conditions has not been complied with.

(4) The Agency may amend, including by attaching new conditions or the amendment of a practice stated to be registered, or withdraw a registration.

(5) Where the Agency has attached a condition to a registration, the registered person shall comply with that condition.

(6) A registration shall not be transferred.

Non-medical imaging practices

16. (1) The Agency shall identify practices involving non-medical imaging exposure, taking into account the practices included in Schedule 5.

(2) The undertaking shall, prior to any exposure in relation to practices involving non-medical imaging exposure: –

(i) provide information on the exposure to the individual to be exposed; and

(ii) seek consent from, unless otherwise provided in legislation, the individual to be exposed.

(3) (a) The Agency shall establish, as appropriate, requirements for practices involving non-medical imaging exposure, including criteria for individual implementation.

(b) For the purposes of establishing requirements under subparagraph (a), the Agency may consult with: –

(i) occupational health services;

(ii) professional bodies of practitioners;

(iii) Health Information and Quality Authority;

(iv) Health Service Executive;

(v) Health and Safety Authority; and

(vi) such other persons or bodies as the Agency sees fit.

(4) (a) For practices involving non-medical imaging exposure using medical radiological equipment: –

(i) the relevant requirements for medical exposure set out in the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018), including those for equipment, optimisation, responsibilities, training, special protection during pregnancy and the appropriate involvement of the medical physics expert shall apply;

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

(iii) where practicable, specific dose constraints shall be put in place.

(b) Before granting authorisation in respect of practices involving non-medical imaging exposure using medical radiological equipment, the Agency shall require the undertaking to submit to it for examination and approval, as part

of the application for an authorisation under Regulation 13, a detailed plan demonstrating that it meets the requirements under subparagraph (a); and

(c) Where the Agency amends, including by attaching or specifying new conditions or amending such a practice stated to be registered or licensed, the Agency may require that the undertaking submit to it an updated plan demonstrating how it will continue to meet the requirements under subparagraph (a).

Radioactive Waste Licences

17. (1) The undertaking shall be responsible for the safety and management of radioactive waste generated from a practice.

(2) The undertaking shall regularly assess, verify and continuously improve, as far as is reasonably achievable, the safety of the radioactive waste management facility or practice in a systematic and verifiable manner. This shall be achieved through an appropriate safety assessment.

(3) The Agency shall require, as part of the licensing of a radioactive waste management facility or a practice involving radioactive waste management, the applicant to carry out a safety assessment covering the development and operation of the practice and the development, operation and decommissioning of the facility or closure of the disposal facility as well as the post-closure phase of the disposal facility. The extent of the safety assessment shall be commensurate with the complexity of the operation and the magnitude of the hazards associated with the radioactive waste, and the facility or practice.

(4) The Agency shall, in considering a decision to grant a licence for a radioactive waste management facility or a practice involving radioactive waste management, so as to identify and reduce uncertainties, have regard to: –

(a) the safety in the facility or of the practice during normal operating conditions, anticipated operational occurrences and design basis accidents;

(b) the required assurance of safety in the facility or of the practice; and

(c) measures in place to prevent accidents and mitigate the consequences of accidents, including verification of physical barriers and the applicant's administrative protection procedures that would have to fail before workers and members of the public would be significantly affected by ionising radiation.

(5) (a) The undertaking shall establish and implement integrated management systems, including quality assurance, which give due priority to safety for overall management of radioactive waste; and

(b) The undertaking shall report periodically to the Agency on such systems for verification in accordance with guidelines published by the Agency.

(6) The undertaking shall make adequate provision, by way of human resources and financial security or any other equivalent means appropriate for the management of the radioactive waste in question, to fulfil their obligations under this Regulation.

(7) The Agency shall make arrangements, as appropriate, for the education and training of its staff, as well as research and development activities to cover the needs of the national programme for radioactive waste management in order to obtain, maintain and to further develop necessary expertise and skills.

(8) This Regulation shall not apply to waste from extractive industries which may be radioactive and which falls within the scope of Directive 2006/21/EC[7].

Licensing of importation and exportation of Radioactive Waste

18. (1) The Agency shall not grant a licence in respect of the exportation for disposal, from the State to another Member State or third country, of radioactive waste generated in the State unless at the time of shipment an agreement, taking into account the criteria established by the European Commission in accordance with Article 16(2) of Directive 2006/117/EURATOM [8]on the supervision and control of shipments of radioactive waste and spent fuel, has entered into force between the State and that other Member State or third country to use a disposal facility in that other Member State or third country.

(2) The Agency shall not grant a licence in respect of the importation for disposal in the State of radioactive waste generated in another Member State or a third country, unless at the time of shipment an agreement, taking into account the criteria established by the Commission in accordance with Article 16(2) of Directive 2006/117/EURATOM, has entered into force between the State and that other Member State or third country to use a disposal facility in the State.

(3) Paragraphs (1) and (2) do not apply to practices involving repatriation of disused sealed sources to a supplier or manufacturer.

(4) Paragraph (1) shall not affect the right of an undertaking in the State to return the radioactive waste after treatment or processing, to its country of origin, where: –

(a) radioactive waste is to be shipped to the undertaking for treatment or processing; or

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[7] OJ L 102, 11.4.2006, p. 15–34
[8] OJ L 337, 5.12.2006, p. 21–32

(b) other material is to be shipped to the undertaking with the purpose of recovering the radioactive waste.

(5) Prior to a shipment to a third country, the Agency shall inform the European Commission of the content of any such agreement and take reasonable measures to be assured that: –

(a) the country of destination has concluded an agreement with the Community covering radioactive waste management or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;

(b) the country of destination has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by the Waste Directive; and

(c) the disposal facility in the country of destination is authorised for the radioactive waste to be shipped, is operating prior to the shipment, and is managed in accordance with the requirements set down in the radioactive waste management and disposal programme of that country of destination.

Release from regulatory control

19. (1) The disposal, recycling or reuse of radioactive materials arising from any authorised practice shall be subject to authorisation.

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

(a) for solid material do not exceed the clearance levels set out in Table A of Schedule 7; or

(b) comply with specific clearance levels and associated requirements for specific materials or for materials originating from specific types of practices; these specific clearance levels shall be established by the Agency.

(3) For 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 them being released from regulatory control is hereby prohibited. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not

subject to this prohibition. The Agency may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling.

Part 3 – SYSTEM OF RADIATION PROTECTION

Section 1 – Tools for optimisation

Dose constraints for occupational and public exposure

20. (1) The Agency shall ensure that, where appropriate, dose constraints are established by undertakings and employers for the purpose of prospective optimisation of protection: –

(a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking: –

(i) in the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking; and

(ii) in all cases the dose constraint shall be established in accordance with guidelines issued by the Agency.

(b) for public exposure, the dose constraint shall be set by the undertaking for the individual dose that members of the public receive from the planned operation of a specified radiation source in accordance with guidelines issued by the Agency.

(2) Dose constraints shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

(3) For practices involving non-medical imaging exposure justified under Regulation 5(1)(b) and not using medical radiological equipment, dose constraints shall be significantly below the dose limit for members of the public under Regulation 27 in accordance with guidelines issued by the Agency.

Reference levels

21. (1) The Agency shall establish reference levels to apply in emergency and existing exposure situations taking into account the range of reference levels set out in Schedule 1. Optimisation of protection shall give priority to exposures above the reference level and shall continue to be implemented below the reference level.

(2) In a nuclear or radiological emergency exposure situation, these reference levels shall be considered in optimising the protection of members of the public, taking account of both radiological protection and socio-economic criteria.

Section 2 - Dose limitation

Age limit for exposed workers

22. Subject to Regulation 26(2), persons under 18 years of age may not be assigned to any work which would result in them meeting the definition of an exposed worker.

Dose limits for occupational exposure

23. (1) Without prejudice to Regulation 25, the undertaking, and in the case of an outside worker, the employer, shall ensure that dose limits for occupational exposure apply to the sum of annual occupational exposures of a worker from all authorised practices, occupational exposure to radon in workplaces requiring notification in accordance with Regulation 66, and other occupational exposure from existing exposure situations in accordance with Parts 3, 7 and 8 of these Regulations. For emergency occupational exposure Regulation 62 shall apply.

(2) The limit on effective dose for occupational exposure shall be 20 mSv in any single year. In special circumstances or for certain exposure situations where the Agency is satisfied that a dose in excess of the annual limit is appropriate, the Agency may authorise a higher effective dose of up to 50 mSv in a single year, provided that the average annual dose over any 5 consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.

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

(a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a single year or 100 mSv in any 5 consecutive years subject to a maximum dose of 50 mSv in a single year;

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

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

(4) In relation to paragraph (3), the undertaking, and in the case of an outside worker, the employer, shall comply with such guidelines as the Agency may issue in

relation to the appropriate procedures to be followed in assessing occupational exposures.

Protection of pregnant and breastfeeding workers

24. (1) As soon as a pregnant worker informs the undertaking or, in the case of an outside worker, the employer, of the pregnancy, the undertaking, and the employer, shall ensure that the protection of the unborn child is comparable with that provided for members of the public.

(2) The undertaking, and the employer, shall ensure that the employment conditions for the pregnant worker are such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during, at least, the remainder of the pregnancy.

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

Specially authorised exposures

25. (1) In exceptional circumstances evaluated case by case, excluding radiological emergencies, the Agency may, where a specific operation so requires, authorise individual occupational exposures of identified workers exceeding the dose limits specified in Regulation 23, provided that such exposures are limited in time, confined to certain working areas and are within maximum exposure levels defined for the particular case by the Agency.

(2) The undertaking shall submit an application to the Agency carefully justifying the proposed exposure and providing information about the risks involved and precautions to be taken.

(3) The undertaking shall permit only Category A workers or spacecraft crew to be subject to exposures authorised under this Regulation.

(4) Apprentices, students, pregnant workers and, if there is a risk of intake or bodily contamination, breast-feeding workers shall be excluded from such exposures.

(5) Before an exposure authorised under this Regulation takes place, the undertaking shall justify such exposures and thoroughly discuss them with the workers concerned, their representatives, the occupational health service and the radiation protection adviser.

(6) The undertaking shall ensure that information about the risks involved and the precautions to be taken during the operation are provided to the relevant workers in advance.

(7) The undertaking shall obtain the worker's consent in writing.

(8) The undertaking shall ensure that all doses relating to such exposures are separately recorded in the medical record referred to in Regulation 47 and in the individual dose record referred to in Regulation 42.

(9) An undertaking shall not, without the agreement of the workers, exclude them from their usual occupation or relocate them on the grounds that the workers have exceeded a dose limit as a result of an exposure authorised under this Regulation.

(10) The Agency shall ensure that the exposure of spacecraft crew above occupational dose limits is managed as a specially authorised exposure.

Dose Limits for apprentices and students

26. (1) The dose limits for apprentices and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Regulation 23.

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

(3) In addition to paragraph (2): –

(a) the limit on the equivalent dose for the lens of the eye of an apprentice or student referred to in that paragraph shall be 15 mSv in a year;

(b) the limit on the equivalent dose for the skin of an apprentice or student referred to in that paragraph shall be 150 mSv in a year, averaged over any area of 1 cm^2 of skin, regardless of the area exposed; and

(c) the limit on the equivalent dose for the extremities of an apprentice or student referred to in that paragraph shall be 150 mSv in a year.

(4) The dose limits for apprentices and students to whom paragraphs (1), (2) and (3) do not apply shall be the same as the dose limits for members of the public as specified in Regulation 27.

Dose Limits for public exposure

27. (1) The dose limits for public exposure shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices.

(2) The limit on the effective dose for public exposure shall be 1 mSv in a year.

(3) Without prejudice to paragraph (2): –

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

(b) the limit on the equivalent dose for the skin of a member of the public shall be 50 mSv in a year, averaged over any 1 cm^2 of skin, regardless of the area exposed; and

(c) the limit on the equivalent dose for the extremities of a member of the public shall be 50 mSv in a year.

Estimation of the Effective and Equivalent Dose

28. (1) For the estimation of effective and equivalent doses, the appropriate standard values and relationships shall be used unless the Agency has authorised the use of equivalent methods.

(2) For external radiation, the operational quantities defined in section 2.3 of ICRP Publication 116[9] shall be used.

[9] Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures, 2010.

Part 4 – PROTECTION OF EXPOSED WORKERS, APPRENTICES AND STUDENTS

Responsibilities of the undertaking and employers

29. (1) The undertaking shall be responsible for assessing and implementing arrangements for the radiation protection of exposed workers, including outside workers, apprentices and students.

(2) In the case of outside workers, the undertaking shall: –

(a) be responsible, either directly or through contractual agreements with the employer of outside workers, for the operational aspects of the radiation protection of outside workers including the sharing of information directly related to the nature of their activities in the undertaking; and

(b) record, after the end of any work activity, in the worker's radiation passbook the data specified in Part B(2) of Schedule 9.

(3) (a) The employer of outside workers shall ensure, either directly or through contractual agreements with the undertaking, that the radiation protection of their outside workers is in accordance with the relevant provisions of these Regulations; and

(b) Before the commencement of any work activity, the employer of an outside worker shall supply in the outside worker's radiation passbook the data specified in Part B(1) of Schedule 9.

(4) Without prejudice to paragraphs (1) to (3), an undertaking, employer or any other organisation shall provide for a clear allocation of responsibilities for the protection of workers in any exposure situation, in particular for the protection of: –

(a) emergency workers;

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

(c) workers who are exposed to radon at work, in the situation specified in Regulation 66; and

(d) self-employed individuals and individuals who work on a voluntary basis.

Arrangements in workplaces

30. (1) For the purposes of radiation protection, the undertaking shall make arrangements for all workplaces where workers are liable to receive an exposure greater than an effective dose of 1 mSv per year or an equivalent dose of 15 mSv per year for the lens of the eye or 50 mSv per year for the skin and extremities. Such arrangements must be appropriate to the nature of the installations and sources and to the magnitude and nature of the risks.

(2) For workplaces specified in Regulation 66, and where the exposure of workers is liable to exceed an effective dose of 6 mSv per year or a corresponding time-integrated radon exposure value determined by the Agency, these shall be managed as a planned exposure situation in accordance with guidelines issued by the Agency.

(3) For workplaces specified in Regulation 66, and where the effective dose to workers is less than or equal to 6 mSv per year or the exposure less than the corresponding time-integrated radon exposure value, the Agency shall require that the exposures are kept under review.

(4) Air operators shall evaluate the extent of exposure to the crew from cosmic radiation in accordance with such guidelines as may be issued by the Agency and shall submit a report of the evaluation to the Agency within one year of the air operator's certificate coming into force.

(5) Where the result of the evaluation referred to in paragraph (4) shows that the effective dose to the crew is liable to exceed 1 mSv per year, the air operator shall: –

(a) assess the exposures of that air crew by methods that have been approved by the Agency;

(b) keep records relating to the assessment referred to in subparagraph (a) in a manner specified by the Agency;

(c) apply the provisions of Regulation 24 to pregnant air crew;

(d) at the request of any member of the air crew concerned make available to that member a copy of any dose record kept for the purposes of subparagraph (b) in relation to that member;

(e) submit the dose records of air crew to the National Dose Register in accordance with guidelines issued by the Agency; and

(f) inform that air crew of health risks involved in their work and their individual dose.

(6) Where the result of this evaluation shows that the effective dose to the crew is liable to exceed 6 mSv per year, the air operator shall in addition to the requirements set out in paragraph (5): –

(a) apply the relevant requirements of these Regulations in accordance with guidelines issued by the Agency; and

(b) organise the working schedules of air crew liable to receive an exposure to cosmic radiation in excess of 6 mSv in a year with a view to reducing their exposures.

Prior Risk Assessment

31. (1) The undertaking shall ensure that all exposures, including those to the population as a whole, from all practices under its control, are kept as low as reasonably achievable, taking into account economic and social factors.

(2) For the purpose of identifying the protective measures needed to restrict exposures to ionising radiation, the undertaking shall, before commencing a practice, make an assessment acceptable to the Agency of the nature and magnitude of the risks of exposure to ionising radiation arising from the practice or from potential exposures resulting from the practice for workers and members of the public who may be affected.

(3) The risk assessment shall be reviewed by the undertaking: –

(a) periodically; and

(b) if circumstances arise in which it has reason to believe that the risk assessment is no longer appropriate, immediately upon those circumstances arising;

and shall be amended by it as it considers appropriate.

(4) Where, in the opinion of the Agency, the assessment provided by the undertaking in accordance with paragraph (2) is insufficient or inadequate, the Agency may, by notice in writing sent to the undertaking require that undertaking to furnish the Agency with the necessary additional information after consultation with a radiation protection adviser.

(5) The undertaking shall, where appropriate, use dose constraints in restricting exposure to ionising radiation pursuant to paragraph (1).

(6) The undertaking shall take account of exposures in other workplaces made available under Regulation 43.

Radiation Safety Procedures

32. (1) For the purpose of enabling work involving ionising radiation to be carried out in accordance with the requirements of these Regulations and, in particular, for the purpose of identifying the manner in which the safety, health and welfare of workers and other persons shall be secured, the undertaking shall, in respect of any controlled area or, where appropriate having regard to the nature of the work carried out there, any supervised area, prepare a statement in writing of such procedures (in these Regulations referred to as "radiation safety procedures") it considers ought to be followed.

(2) Such a statement shall have regard to the radiological risks involved and the nature of the activities concerned and, in particular, to the prior risk assessments carried out under Regulation 31 by the undertaking.

(3) The radiation safety procedures shall be reviewed by the undertaking periodically, and immediately upon circumstances arising which give the undertaking reason to believe any of the procedures are no longer appropriate. The procedures shall then be amended by the undertaking as it considers appropriate.

(4) When the Agency is satisfied that any radiation safety procedures are inadequate in a material way, it may give a direction to the undertaking concerned to amend the procedures after consultation with a radiation protection adviser and the undertaking shall comply with the direction within 30 days from the date of the direction being given by the Agency.

(5) The undertaking shall take all reasonable steps to ensure that the provisions of the radiation safety procedures prepared by it are observed.

(6) The undertaking shall ensure that the radiation safety procedures prepared by it are brought to the attention of and made available to the exposed workers including outside workers, apprentices and students concerned and other persons who may be affected by them.

Consultations with a Radiation Protection Adviser

33. (1) For the purposes of meeting its responsibilities under Regulation 29(1), the undertaking shall seek advice from a radiation protection adviser or advisers within their areas of competence, and approved under Regulation 79, and shall provide the radiation protection adviser or advisers with access, adequate information and facilities for the discharge of his or her functions in relation to the following: –

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

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

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

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

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

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

(a) optimisation and establishment of appropriate dose constraints;

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

(c) categorisation of controlled and supervised work areas;

(d) classification of workers;

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

(f) appropriate radiation monitoring instrumentation;

(g) quality assurance;

(h) environmental monitoring programme;

(i) arrangements for radioactive waste management;

(j) arrangements for the prevention of accidents and incidents;

(k) preparedness and response in emergency exposure situations;

(l) training and retraining programmes for exposed workers;

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

(n) employment conditions for pregnant and breastfeeding workers; and

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

(3) Upon consultation with a radiation protection adviser or advisers, the undertaking shall devise and submit to the Agency as part of a licence application, renewal or amendment, the agreed arrangements with the named radiation protection adviser or advisers detailing the provisions that are in place to meet the requirements of these Regulations.

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

Role of Radiation Protection Officer

34. (1) The undertaking shall provide the radiation protection officer, as provided for in Regulation 80, with adequate information and facilities for them to discharge their functions.

(2) The radiation protection officer shall report directly to the undertaking.

(3) Depending on the nature of the practice, the tasks of the radiation protection officer in assisting the undertaking, may include the following: –

(a) ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures and working instructions;

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

(c) maintaining adequate records of all radiation sources;

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

(e) supervising the implementation of the personal monitoring programme;

(f) supervising the implementation of the health surveillance programme;

(g) providing new workers with an appropriate introduction to specified procedures and working instructions;

(h) giving advice and comments on work plans;

(i) establishing work plans;

(j) providing reports to the local management;

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

(l) information and training of exposed workers; and

(m) liaising with the radiation protection adviser.

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

Radiation Protection Education, Training and Information

35. (1) Every undertaking, and in the case of outside workers, the employer, must ensure that: –

(a) all exposed workers, apprentices and students who are engaged in work with ionising radiation, including radioactive waste management, are given appropriate education, training and information in the field of radiation protection and receive such information and instruction as is suitable and sufficient for them to know: –

(i) the risks to health created by exposure to ionising radiation;

(ii) the general principles of radiation protection and the specific radiation protection procedures and precautions in connection with the operational and working conditions of the work with ionising radiation to which they may be assigned;

(iii) the importance of providing input to risk assessments of the operational and working conditions of the work with ionising radiation to which they may be assigned for the purposes of devising relevant radiation protection procedures;

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

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

(b) adequate information is given to other persons who are not directly engaged with the work with ionising radiation carried out by the undertaking or employer to ensure their health and safety so far as is reasonably practicable;

(c) all workers, apprentices and students who are engaged in work with ionising radiation are informed of the possible risk arising from ionising radiation to the unborn child and to a nursing infant and of the importance of those workers making an early declaration of pregnancy and the intention to breast feed; and

(d) all exposed workers, apprentices and students including outside workers who are engaged in work in a controlled area as classified under Regulation 36 are given specific training in connection with the characteristics of the workplace and the activities within it.

(2) In addition to the requirements in paragraph (1), undertakings and, in the case of outside workers, employers, engaged in work with ionising radiation involving a high-activity sealed source must ensure that the information and training given to exposed workers includes: –

(a) specific requirements for the safe management and security and control of high-activity sealed sources for the purpose of preparing such employees for any events which may affect their radiation protection;

(b) particular emphasis on the necessary safety and security requirements in connection with high-activity sealed sources; and

(c) specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

(3) The provision of education, training and information under this Regulation shall be repeated at appropriate intervals and documented in accordance with guidelines issued by the Agency.

Classification of workplaces

36. (1) The undertaking shall, having regard to an assessment made by it, in accordance with Regulation 31, of the expected annual doses and the probability and magnitude of potential exposures classify as a controlled area any area under its control in which any person working in the area is liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities.

(2) The undertaking shall, having regard to an assessment made by it, in accordance with Regulation 31, of the expected annual doses and the probability and magnitude of potential exposures classify as a supervised area any area under its control, not being classified as a controlled area, in which any person working in the area is liable to receive an effective dose greater than 1 mSv per year or an equivalent dose not greater than 15 mSv per year for the lens of the eye or greater than 50 mSv per year for skin and extremities.

(3) The undertaking is responsible for implementing these responsibilities and shall keep under review the working conditions in controlled and supervised areas and, if appropriate, revise the classification of the areas concerned taking into account the advice provided by a radiation protection adviser.

Requirements for Controlled and Supervised Areas

37. (1) The undertaking shall ensure in the case of a controlled area that: –

(a) the area is physically demarcated or, where this is not reasonably practicable, delineated by some other suitable means, and suitable and sufficient signs indicating that it is a controlled area and the nature of the radiological sources and their inherent risks are displayed;

(b) access is restricted in accordance with paragraph (2) to individuals who have received appropriate instructions and is controlled in accordance with written radiation safety procedures or working instructions, which are appropriate to the radiological risk associated with the sources and the operations involved;

(c) wherever there is a significant risk of the spread of radioactive contamination, specific arrangements are made, including arrangements for the access and exit of individuals and goods and for monitoring contamination within the controlled area and, where appropriate, in the adjacent area;

(d) taking into account the nature and extent of the radiological risks in the controlled area, radiological surveillance of the working environment is organised in accordance with the provisions of Regulation 38;

(e) any person working in the controlled area, including outside workers shall receive specific training in connection with the characteristics of the workplace and the activities, and shall be provided with the appropriate personal protective equipment;

(f) for Category A outside workers required to enter the controlled area, confirm that the outside worker concerned has been passed as medically fit for the activities to be assigned to the worker; and

(g) for Category B outside workers, confirm whether the categorisation is appropriate in relation to the doses liable to be received within the undertaking.

(2) The undertaking who has classified an area as a controlled area shall not permit any person to enter or remain in such an area unless that person is: –

(a) a Category A worker who has been determined as fit to perform their duties pursuant to a medical classification under Regulation 46;

(b) a Category B worker, following suitable written arrangements for the purpose of ensuring that the person does not receive in any calendar year a cumulative dose of ionising radiation which would require that person to be designated as a Category A worker;

(c) an outside worker, for whom the undertaking shall take all reasonable steps to ensure: –

(i) is subject to individual dose assessment pursuant to Regulation 41;

(ii) has been provided with and has been trained to use any personal protective equipment that may be necessary pursuant to subparagraph (1)(e);

(iii) has received any specific training required pursuant to Regulation 35;

(iv) where such a worker has been categorised as Category A, he or she has been determined as fit to perform their duties pursuant to a medical classification under Regulation 46; and

(v) where such a worker has been categorised as Category B, he or she must follow suitable written arrangements for the purpose of ensuring that the person does not receive in any calendar year a cumulative dose of ionising radiation which would require that person to be categorised as Category A.

(d) (i) any other person not categorised as an exposed worker, following suitable written arrangements for the purpose of ensuring that the person does not receive in any calendar year a dose of ionising radiation exceeding any relevant dose limit for a member of the public; and

(ii) the undertaking can demonstrate by personal dose monitoring or other suitable measurements that the dose to the person does not exceed any relevant dose limit for a member of the public.

(3) The undertaking shall ensure in the case of a supervised area that: –

(a) as a minimum, taking into account the nature and extent of the radiological risks in the supervised area, radiological surveillance of the working environment is organised in accordance with the provisions of Regulation 38; and

(b) if appropriate, signs indicating that it is a supervised area and the nature of the radiological sources and their inherent risks are displayed.

(4) Any person working in the supervised area, including outside workers, shall receive working instructions or radiation safety procedures appropriate to the radiological risk associated with the sources and the operations involved.

(5) The undertaking, in fulfilling its obligations under paragraphs (1) to (4), shall consult with the radiation protection adviser.

(6) Without prejudice to the generality of paragraph (1), the arrangements required by that paragraph must, where appropriate, include: –

(a) the provision of suitable and sufficient washing and changing facilities for persons who enter or leave any controlled or supervised area;

(b) the proper maintenance of such washing and changing facilities;

(c) the prohibition of eating, drinking or smoking or similar activity likely to result in the ingestion, inhalation or absorption of a radioactive substance by any employee or outside worker in a controlled area; and

(d) the means for monitoring contamination: —

(i) on any person, article or goods leaving a controlled area;

(ii) within the controlled area and, where appropriate, in the adjacent area.

(7) An undertaking that has designated an area as a controlled area must, in relation to an outside worker, ensure that: –

(a) the outside worker is subject to arrangements for estimating the dose of ionising radiation received by that worker whilst in the controlled area;

(b) as soon as is reasonably practicable after the services carried out by that outside worker in that controlled area are completed, an estimate of the dose received by that outside worker is entered into that worker's radiation passbook; and

(c) when the radiation passbook of the outside worker is in the possession of that employer, the passbook is made available to that outside worker upon request.

(8) The employers of outside workers shall ensure either directly or through contractual arrangements with the undertaking that the radiation protection of their workers is equivalent to the protection afforded to exposed workers employed on a permanent basis by the undertaking.

Radiological surveillance of the workplace

38. (1) Radiological surveillance pursuant to Regulations 37(1)(d) and 37(3)(a) shall comprise, where appropriate, the measurement of: –

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

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

(c) radon by a radon measurement service.

(2) The undertaking shall, having regard to any relevant guidelines issued by the Agency, ensure that all measuring instruments used to carry out the surveillance referred to in paragraph (1) are: fit for the intended purpose, properly maintained and individually calibrated traceable to appropriate national standards.

(3) The undertaking shall ensure that: –

(a) all measuring instruments including those used for assuring in Quality Assurance programmes are individually calibrated before first use and annually thereafter using sources or equipment traceable to appropriate national standards; and

(b) the maintenance, examination and calibration of measuring instruments are carried out by persons who have knowledge of and understanding of currently accepted testing standards and relevant technical guidance in relation to the types of monitoring equipment.

(4) The undertaking shall: –

(a) make suitable records of the results of the measurements referred to in paragraph (1) and of the maintenance and calibrations carried out in accordance with paragraphs (2) and (3);

(b) ensure that the records made pursuant to subparagraph (a) are made available to the radiation protection adviser if he or she requests them; and

(c) maintain each of the records referred to in subparagraph (a) for a period of at least 5 years from the date on which it is made.

(5) The results of the measurement referred to in paragraph (1) shall be recorded and shall be used, if necessary, for estimating individual doses as provided for in Regulation 41.

Part 5 – CATEGORISATION AND MONITORING OF WORKERS

Categorisation of exposed workers

39. (1) Prior to the commencement of any work activity which may give rise to an exposure, the undertaking, and in the case of outside workers, the employer, shall categorise: –

(a) as a Category A worker, an exposed worker who is liable to receive an effective dose greater than 6 mSv in a year or an equivalent dose greater than 15 mSv per year for the lens of the eye, or greater than 150 mSv per year for skin and extremities; and

(b) as a Category B worker, an exposed worker who is liable to receive an effective dose greater than 1 mSv but less than 6 mSv in a year or an equivalent dose not greater than 15 mSv per year for the lens of the eye, or greater than 50 mSv but less than 150 mSv per year for skin and extremities.

(2) The categorisation shall take into account potential exposures including, where relevant, the results of any individual radiological monitoring disclosed under Regulation 43(1)(d).

(3) In the case of outside workers, the undertaking shall determine whether the categorisation of the outside worker is appropriate in relation to the doses liable to be received within the undertaking.

(4) The undertaking, and in the case of outside workers, the employer, shall immediately inform the worker that they have been categorised as a Category A or B worker as the case may be.

(5) The undertaking, and in the case of outside workers, the employer, shall regularly review this categorisation on the basis of working conditions and medical surveillance pursuant to Regulation 45.

Operational protection of apprentices and students

40. (1) The exposure conditions and operational protection provided by the undertaking, and in the case of outside workers, the employer, for apprentices and students aged 18 years or over referred to in Regulation 26(1) shall be equivalent to that of exposed workers of Category A or B, as appropriate.

(2) The exposure conditions and operational protection provided by the undertaking, and in the case of outside workers, the employer, for apprentices and students aged

between 16 years or more but less than 18 years referred to in Regulation 26(2) shall be equivalent to that of exposed workers of Category B.

Individual Monitoring

41. (1) The undertaking, and in the case of outside workers, the employer, shall ensure that: –

(a) individual dose monitoring based on individual measurements is carried out by an approved dosimetry service, or as appropriate, by a radon measurement service, for all exposed workers, outside workers, apprentices and students;

(b) in cases where exposed workers, outside workers, apprentices and students are liable to receive significant internal exposure or significant exposure of the lens of the eye or extremities, an adequate system for monitoring shall be set up; in identifying such cases, the undertaking, and in the case of outside workers, the employer, shall take account of any guidelines issued by the Agency in that regard;

(c) in the case of accidental exposure, the relevant doses and their distribution in the body are assessed;

(d) in the case of emergency occupational exposure, individual monitoring or assessment of the individual doses of emergency workers is carried out as appropriate to the circumstances; and

(e) in the case of specially authorised exposures, individual dose monitoring of Category A exposed workers or spacecraft crew, based on individual measurements is carried out.

(2) Without prejudice to paragraph (3), in cases where an individual dose measurement is not possible or inadequate either because of loss or damage to a dosemeter or for any other reason, the undertaking, and in the case of outside workers, the employer, shall estimate the dose to the exposed worker, outside worker, apprentice or student either: –

(a) from individual measurements made on other exposed workers, outside workers, apprentices and students;

(b) from the results of the radiological surveillance of the workplace provided for in Regulation 38; or

(c) on the basis of calculation methods approved by the Agency.

(3) Where there is reason to believe that the dose received by an exposed worker, outside worker, apprentice or student is much greater or less than that recorded on

the dosemeter, the undertaking, and in the case of outside workers, the employer, shall also comply with the requirements specified in paragraph (2).

(4) Where the Agency considers that any estimation made in accordance with paragraph (2) is inadequate, it may direct, in writing, the undertaking, and in the case of outside workers, the employer, to carry out whatever additional investigations the Agency considers necessary in order to establish the estimated dose, and the undertaking, and in the case of outside workers, the employer, shall comply with that direction.

Recording and Reporting of Results

42. (1) The undertaking, and in the case of outside workers, the employer, shall make arrangements so as to ensure that: –

(a) a record containing the results of individual monitoring carried out pursuant to Regulation 41 is made for each exposed worker, outside worker, apprentice or student;

(b) the record referred to in subparagraph (a) contains: –

(i) data on the worker's identity prescribed in Part A of Schedule 9;

(ii) a record of the individual doses measured or estimated, as the case may be, pursuant to Regulation 41;

(iii) in the case of accidental exposures, specially authorised exposures or emergency exposures, the reports relating to the circumstances and the action taken; and

(iv) the results of workplace monitoring used to assess individual doses, where necessary;

(c) the record referred to in subparagraph (a) shall take account of the results of any individual radiological monitoring disclosed under Regulation 43(1)(d); and

(d) the undertaking, and in the case of outside workers, the employer, shall request, in writing to the National Dose Register, a unique identification number for the exposed worker, outside worker, apprentice or student for the purposes of making a record under subparagraph (a).

(2) The undertaking, and in the case of outside workers, the employer, shall ensure that: –

(a) the record referred to in subparagraph (1)(a) is submitted within 3 months, or such longer period with the agreement of the Agency, of the end of each calendar year to the National Dose Register in accordance with guidelines issued by the Agency; and

(b) where the results of monitoring or assessment of an individual's dose are amended subsequent to submission, the amended record shall be submitted to the National Dose Register without delay.

(3) The dose records in relation to accidental exposure, specially authorised exposure, emergency occupational exposure and occupational exposure from radon liable to exceed an effective dose of 6 mSv per year shall be identified in the dose record referred to in subparagraph (1)(a).

(4) In the case of an accidental exposure, the undertaking and in the case of an outside worker, the employer shall ensure that the results of individual monitoring and dose assessments are communicated to the individual and submitted to the Agency without delay.

(5) On receipt of a disclosure under Regulation 50(1)(e), the undertaking shall request in writing, from each undertaking identified in the disclosure, the record containing the results of individual monitoring made under subparagraph (1)(a).

(6) The undertaking, and in the case of outside workers, the employer, shall make arrangements to retain the record referred to in subparagraph (1)(a) during the period of the working life involving exposure to ionising radiation of the worker concerned and afterwards until they have or would have attained the age of 75 years, but, in any case not less than 30 years after termination of the work involving exposure to ionising radiation.

Access to the Results of Individual Monitoring

43. (1) The undertaking, and in the case of outside workers, the employer, shall ensure that the record referred to in Regulation 42 is made available, on request in writing to: –

(a) the Agency;

(b) the worker concerned in accordance with paragraph (2);

(c) the occupational health service in order for it to interpret the implications of the results for human health as provided for in Regulation 45; and

(d) an undertaking pursuant to a request under Regulation 42(5).

(2) The undertaking, and in the case of outside workers, the employer, shall at the request of any worker employed by it or of a person formerly employed by it, make available to that worker or person a copy of the dose record provided for the purposes of Regulation 42 in respect of that worker or person. This record shall include the results of measurements which may have been used in estimating doses or the results of the assessments of doses made as a result of radiological surveillance of the workplace.

(3) Where a record under Regulation 42(1) is made available pursuant to subparagraph (1)(d), the undertakings shall periodically exchange in writing the individual dose data as set out in Part A of Schedule 9 so as to control the further exposure of workers. This exchange shall be at intervals sufficient to ensure compliance with dose limits and not less than every 3 months commencing from the date of disclosure under subparagraph (1)(d).

National Dose Register

44. (1) The Agency shall establish and maintain a data system for individual radiological monitoring of exposed workers (in these Regulations called "the National Dose Register").

(2) The National Dose Register shall comprise the following sections: –

(a) particulars concerning the worker's identity;

(b) particulars concerning the medical surveillance of the worker;

(c) particulars concerning the undertaking of the worker, and in the case of an outside worker, the employer of the worker; and

(d) the results of the individual monitoring of the exposed worker.

(3) The National Dose Register shall: –

(a) cover as a minimum the data listed in Part A of Schedule 9;

(b) include the issuance of individual radiological monitoring documents in the form of a radiation passbook for outside workers in accordance with the requirements of Schedule 9;

(c) assign a unique identification number to each exposed worker for the purposes of identifying an individual worker to enable the recording of individual radiological monitoring;

(d) make the unique identification number referred to in paragraph (5) available in writing to an undertaking and, in the case of outside workers, the employer pursuant to a request under Regulation 42(1)(d);

(e) make available any record held on an individual worker following a request in writing from that worker;

(f) make available an individual's results under subparagraph (2)(d) to an undertaking or, in the case of an outside worker, the employer, following a request in writing; and

(g) retain records submitted under Regulation 42 during the period of the working life involving exposure to ionising radiation of the worker concerned and afterwards until they have or would have attained the age of 75 years but, in any case not less than 30 years after termination of the work involving exposure to ionising radiation.

Medical surveillance of exposed workers

45. (1) This Regulation shall apply to Category A workers and any worker whom an undertaking, and in the case of outside workers, the employer, intends to classify as a Category A worker.

(2) Without prejudice to the duties of the undertaking under these Regulations, the undertaking, and in the case of outside workers, the employer, shall appoint an occupational health service to carry out medical surveillance of each worker to whom this Regulation applies who is employed or retained by it.

(3) The medical surveillance referred to in paragraph (2) shall be based on the principles that govern occupational medicine and must allow for ascertaining the state of health of workers under surveillance as regards their fitness for the tasks assigned to them.

(4) The undertaking, and in the case of outside workers, the employer, shall provide the occupational health service with access to any relevant information and records that this service may require including information and records with regard to the environmental conditions existing in the working premises.

(5) The medical surveillance referred to in paragraphs (2) and (3) shall include: –

(a) a medical examination of the worker prior to his or her being employed or classified as a Category A worker; the purpose of this examination shall be to determine the worker's fitness for a post as a Category A worker for which he or she is being considered; and

(b) periodic reviews of his or her health.

(6) The review referred to in subparagraph (5)(b) shall be conducted at least once a year and at such lesser intervals as the occupational health service considers necessary and shall be conducted for the purpose of determining whether or not the Category A worker is fit to perform his or her duties. The nature of such a review shall depend on the type of work and on the individual's state of health.

(7) If the occupational health service indicates the need for medical surveillance to be continued for such a period as the occupational health service specifies after the worker concerned has ceased to be employed, the undertaking, and in the case of outside workers, the employer, shall arrange for the medical surveillance under this Regulation to be continued by the occupational health service as specified in order to safeguard the health of the person concerned.

Medical classification

46. (1) The occupational health service shall adopt the following medical classification with respect to fitness for work as a Category A worker: –

(a) Fit;

(b) Fit, subject to certain conditions; or

(c) Unfit.

(2) If the occupational health service has determined that a worker is fit for work subject to certain conditions, the undertaking, and in the case of outside workers, the employer, shall not employ or retain or continue to employ or retain the worker as a Category A worker unless it complies with those conditions.

(3) The undertaking, and in the case of outside workers, the employer, shall ensure that no worker is employed or classified for any period in a particular post as a Category A worker if the medical findings of the occupational health service deem the worker unfit for that post.

Medical records

47. (1) The undertaking, and in the case of outside workers, the employer, shall ensure that a medical record is made for each Category A worker and kept up to date so long as the worker remains a worker in that category.

(2) Thereafter, the medical record shall be retained until the individual has or would have attained 75 years of age, but in any case no less than 30 years after termination of the work involving exposure to ionising radiation.

(3) The medical record shall include: –

(a) the worker's full name, gender, date of birth, permanent address and unique identifier;

(b) the date of the worker's commencement as a Category A worker in his or her present employment;

(c) the date of the last medical examination or health review carried out under these Regulations in respect of the worker;

(d) the results of the medical examinations prior to employment or classification as a Category A worker and the results of the periodic health reviews;

(e) the record of the radiation doses received by the worker in accordance with Regulation 42;

(f) the comments of the occupational health service as to the worker's fitness to work or as to the conditions to which the worker should be subject; and

(g) a signature on behalf of the occupational health service.

Special medical surveillance

48. (1) The undertaking, and in the case of outside workers, the employer, shall provide such medical surveillance in addition to that required by Regulation 45 as is appropriate in each case where a worker, outside worker, apprentice or student has received an exposure in excess of the dose limits specified in Regulations 23, 25 and 26.

(2) In the case of exposed individuals referred to in paragraph (1), the undertaking, and in the case of outside workers, the employer, shall ensure that any determination by it with regard to the subsequent conditions for the exposure of these persons is approved of by the occupational health service.

(3) In addition to the medical surveillance of exposed workers provided for in these Regulations, the undertaking, and in the case of outside workers, the employer, shall make provision for any further actions in relation to the health protection of the exposed individual considered necessary by the occupational health service, such as further examinations, decontamination measures, urgent remedial treatment or other identified actions.

Appeals in relation to medical surveillance

49. (1) Any person aggrieved by: –

(a) a decision made by the occupational health service under Regulation 46 with respect to fitness for work;

(b) a decision made by the undertaking, and in the case of outside workers, the employer, as to the extent of medical surveillance to be provided under Regulation 48(3); or

(c) a determination made by the undertaking, and in the case of outside workers, the employer, under Regulation 46(3);

may appeal to the Circuit Court against that decision or determination.

(2) The Circuit Court, on hearing of an appeal under paragraph (1), may, as it thinks appropriate, affirm or set aside the decision or determination concerned or modify it in such a manner as it thinks fit.

Duties of Exposed Workers, Apprentices, Students and Employers

50. (1) An exposed worker, outside worker, apprentice or student shall: –

(a) not knowingly expose himself or herself or any other person to ionising radiation to an extent greater than is reasonably necessary for the purpose of his or her work, and shall exercise reasonable care while carrying out such work;

(b) make full and proper use of any personal protective equipment provided, including personal dosemeters;

(c) forthwith report to the undertaking or in the case of outside workers, the employer, any defect he or she discovers in any such equipment;

(d) notify the undertaking or in the case of outside workers, the employer of any suspected exposure likely to cause a breach of any dose limit specified in Regulations 23, 25 and 26 or any other unusual occurrence causing or likely to cause exposure in excess of such a limit; and

(e) with the exception of outside workers, prior to the commencement of the work activity, disclose in writing to the undertaking details in accordance with Part A(4) of Schedule 9 of other undertakings under whose control the worker is liable to be exposed.

(2) An employer shall ensure that each outside worker employed by it is provided with an individual radiation passbook, which shall be non-transferable, and prior to the commencement of any activity, shall supply the data specified in Part B(1) of Schedule 9.

(3) A self-employed outside worker shall furnish himself or herself with a radiation passbook, which shall be non-transferable, and in which there shall be entered the particulars specified in Part B(1) of Schedule 9.

(4) An employer or a self-employed outside worker shall make suitable arrangements to ensure that the particulars entered in the radiation passbook concerned are kept up to date.

(5) An outside worker shall: –

(a) take reasonable care of the radiation passbook provided or made available to him or her, and, in the case where he or she is an employed outside worker, if it is lost, report the loss forthwith to the employer;

(b) not misuse the radiation passbook provided or made available to him or her or falsify or attempt to falsify any of the information contained in it;

(c) in the case where he or she is an employed outside worker, return the radiation passbook to the employer immediately on ceasing to be employed or retained by that undertaking or when the radiation passbook is full and requires renewal; and

(d) make the radiation passbook available to the undertaking on whose premises he or she carries out work.

(6) Where an outside worker who has lost a passbook subsequently finds it, he or she shall, in the case he or she is an employed outside worker, forthwith report its finding to the employer concerned and return that passbook to the undertaking.

Part 6 – PUBLIC EXPOSURES

Operational protection of members of the public

51. (1) Undertakings shall take such measures as are necessary to ensure the operational protection of members of the public in normal circumstances having regard to the relevant provisions of these Regulations.

(2) For the purposes of these Regulations, "operational protection of members of the public" means, in normal circumstances, all arrangements and surveys for detecting and eliminating the factors which, in the course of any operation, may result in actual or potential exposure to members of the public exceeding the relevant dose constraint such that the exposure from all authorised practices is not liable to exceed 1 mSv in a year.

(3) For relevant workplaces, the Agency shall before granting a registration or a licence in respect of a practice or amending any condition attached to a registration or specified in a licence require the undertaking to submit to it for examination and approval: –

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

(b) a statement of planned arrangements to ensure adequate protection against any exposure or radioactive contamination liable to extend beyond the perimeter of the workplaces or radioactive contamination liable to extend to the ground beneath the facility;

(c) plans for the discharge of radioactive effluents;

(d) the results of a screening assessment of the doses liable to be received by the population as a result of any practice carried out by it; and

(e) a statement of planned measures to control the access of members of the public to the facility.

(4) The Agency shall, where appropriate, establish limits and conditions on the quantities of radionuclides discharged to air or water during a specified period, which shall take into account: –

(i) the results of the optimisation of radiation protection;

(ii) good practice in the operation of similar facilities; and

(iii) where appropriate, results of generic screening assessment based on internationally recognised scientific guidance, where such an assessment has been required by the Agency.

Tasks for the undertaking

52. The undertaking shall ensure that a practice in respect of which an authorisation has been granted is carried out in accordance with the principles of health protection of members of the public as they relate to radiation protection and in particular shall do the following things within its facility: –

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

(b) operate adequate equipment and procedures for measuring and assessing, as appropriate, exposure of members of the public and radioactive contamination of the environment;

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

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

Monitoring of radioactive discharges

53. For practices specified by the Agency, the undertaking shall: –

(a) monitor or evaluate, where appropriate, the radioactive airborne or liquid discharges into the environment in normal operation, and report the results to the Agency;

(b) maintain records of the monitoring referred to in paragraph (a);

(c) limit the quantities of radionuclides discharged to air or water during a period specified by the Agency;

(d) make an assessment of the doses received by the population as a result of any practice carried out by it, in accordance with Regulation 54; and

(e) make and keep records of the assessments referred to in paragraph (d) and make these available on request to all stakeholders relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.

Estimation of doses to members of the public

54. (1) Where the Agency specifies that a realistic dose assessment is required, undertakings shall ensure that the estimates of doses to the representative person include an assessment of: –

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

(b) the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity concentrations of these radionuclides in food and drinking water or other relevant environmental media; and

(c) the doses that the representative person, as identified in paragraph (a), is liable to receive.

(2) In the aftermath of a radiological emergency where there are lasting exposures resulting from the after-effects of the emergency, or in instances of lasting exposure resulting from a practice which has ceased to be carried out, undertakings shall ensure the provisions of Regulation 61 are met when assessing public exposures.

Part 7 – EMERGENCY PREPAREDNESS AND RESPONSE

National Plan for Nuclear and Radiological Emergency Exposures

55. (1)(a) The Minister shall, after consultation with such other Minister of the Government (if any) who might, in the opinion of the Minister, be concerned in the matter, establish and maintain a plan for the national response to nuclear and radiological emergency exposure situations.

(b) the "National Plan for Nuclear and Radiological Emergency Exposures" (in these Regulations referred to as "the National Plan") shall be based on, and commensurate with, an assessment of potential emergency exposure situations that may arise from events taking place either inside or outside the State.

(2) The National Plan shall set out: –

(a) the organisation at national level of appropriate protective measures including the elements set out in Schedule 15;

(b) procedures for providing information to the public in the event of a national emergency exposure situation, including the elements set out in Schedule 16, Part B;

(c) (i) provision for cooperation and coordination activities with other Member States, relevant third countries and relevant international organisations;

(ii) these activities shall not prevent or delay any necessary actions to be taken at national level; and

(d) provision for the transition from a national emergency exposure situation to an existing exposure situation.

(3) The Agency shall arrange for the carrying out of drills and exercises to test the effectiveness of the protective measures set out in the National Plan at suitable intervals.

(4) In the aftermath of a nuclear or radiological emergency exposure situation arising from events taking place either inside or outside the State, the Agency shall record and review the consequences of the nuclear or radiological emergency exposure situation and assess the effectiveness of the protective measures and report those findings to the Minister at the earliest opportunity.

(5) The Minister shall periodically review the National Plan to take account of changes or lessons identified from exercises and events.

(6) The Minister will establish and maintain a dedicated website providing information to the public likely to be affected by an emergency exposure situation. The website will include the elements set out in Schedule 16, Part A.

Contaminated Areas and Existing Exposure Situations

56. (1) In the aftermath of a nuclear or radiological emergency exposure situation, where there are lasting exposures resulting from the after-effects of the emergency, or in instances of lasting exposure resulting from a practice which has ceased to be carried out, or where there is lasting elevated exposure due to natural radiation sources, the Minister shall develop a strategy for contaminated areas and existing exposure situations, aimed at minimising the lasting exposures, which shall include, where applicable, the following elements: –

(a) objectives, including long-term goals pursued by the response and corresponding reference levels in accordance with Regulation 21;

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

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

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

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

(f) controls on commodities incorporating radionuclides from the contaminated area;

(g) consideration of the need to ensure that the form, scale and duration of all protective measures in the strategy are optimised; and

(h) provision for cooperation, where appropriate, with other Member States and relevant third countries in the transition from an emergency exposure situation to an existing exposure situation.

(2) In areas with long-lasting residual contamination or other existing exposure situations where it has been decided to allow habitation and the resumption of social and economic activities, the Agency, in consultation with stakeholders, including

residents and property owners, shall ensure that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including: –

(a) establishment of appropriate reference levels, commensurate with the characteristics of the exposure situation, taking into account the reference levels for public exposure laid down in Schedule 1;

(b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, including the provision by the Agency of expert advice and information and appropriate monitoring;

(c) if appropriate, remediation measures; and

(d) if appropriate, delineated areas.

(3) For existing exposure situations, the Agency shall: –

(a) assess the distribution of doses that has resulted from the implementation of the strategy;

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

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

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

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

(4) For existing exposure situations arising from exposure to naturally-occurring radionuclides in commodities excluding food and drinking water, the Minister shall develop a Strategy aimed at minimising the lasting exposures, which shall include, where applicable, the following elements: –

(a) objectives, including long-term goals pursued by the strategy and corresponding reference levels in accordance with Regulation 21;

(b) identification of the affected commodities and of the affected members of the public;

(c) assessment of the exposure of different groups in the population;

(d) consideration of the need for and extent of controls to be applied to the affected commodities; and

(e) consideration of the need to ensure that the form, scale and duration of all protective measures in the strategy are optimised.

Major Emergency Plans

57. (1) Any plans prepared by local authorities to deal with major emergencies shall include provision for the organisation of the emergency response actions and protective measures which may be required to be taken within their local government area in the event of a radiological emergency exposure situation.

(2) Such plans shall include the elements set out in Schedule 15 in line with guidelines prepared by the Agency and include provision for the transition from an emergency exposure situation to an existing exposure situation.

(3) Any local authority responsible for the organisation of emergency response or protective measures shall provide radiological monitoring and medical surveillance for those involved in the taking of the measures, as appropriate.

(4) Local authorities shall ensure that any such plans are tested, reviewed and, as appropriate, revised at regular intervals.

Emergency Preparedness for Licensed Undertakings

58. (1) In the case of a practice which is subject to licence, the undertaking shall: –

(a) evaluate the possibility of a radiological emergency resulting from the practice and the potential for exposure of workers and members of the public; and

(b) based on the evaluation, prepare an emergency response plan following consultation with a radiation protection adviser, the Agency and, where appropriate, the local authority within whose local government area the undertaking carries on the practice (in these Regulations referred to as "the relevant local authority").

(2) The undertaking shall: –

(a) submit a copy of the emergency response plan referred to in subparagraph (1)(b) to the Agency and, where appropriate, the relevant local authority as soon as may be practicable after it is prepared;

(b) carry out drills and exercises to test the emergency response plan at regular intervals;

(c) ensure that, where appropriate, suitably trained personnel are available for technical, medical and health intervention; and

(d) ensure that any person under the control of the undertaking who may be involved in or may be affected by the emergency response plan is given suitable instruction in the arrangements of the plan.

Duty of Undertaking to inform members of the public likely to be affected in the event of a radiological exposure situation

59. (1) Where the evaluation referred to in Regulation 58 identifies the potential for members of the public to be exposed, the undertaking shall make provisions to ensure that the members of the public likely to be affected are given information about the health protection measures applicable to them and the action they should take in the event of such an exposure.

(2) The information supplied pursuant to paragraph (1) shall include, at least, the following: –

(a) basic facts about radioactivity and its effects on human beings and the environment;

(b) the various types of exposure covered and their consequences for the public and the environment; and

(c) measures envisaged to alert, protect and assist the public in the event of an exposure.

(3) The undertaking shall make provision for ensuring that the information referred to in paragraph (2) is reviewed every 3 years and whenever significant changes in the arrangements that it describes take place, and that it is made permanently available to the public.

Emergency response for Undertakings

60. (1) An undertaking carrying on a practice shall, in accordance with guidelines issued by the Agency, immediately upon a radiological emergency arising from the practice, notify the Agency of the emergency. At the same time the undertaking shall inform the local emergency services of the circumstances with respect to the emergency.

(2) In relation to such an emergency, the undertaking shall make an initial provisional assessment of the circumstances surrounding, and the possible consequences of, the emergency and submit a statement in writing of that assessment to the Agency as soon as possible but not later than 24 hours after the commencement of the emergency.

(3) The undertaking shall undertake or assist with any protective measures appropriate to the circumstances of the radiological emergency.

(4) The protective measures referred to in paragraph (3) shall include, if the situation so requires, protective measures related to: –

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

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

(c) individuals, to reduce exposure and, where necessary, organise the medical treatment of those affected.

(5) The undertaking and the relevant local authority or authorities, in whose local government area or areas protective measures are being taken, shall co-operate with one another with regard to those measures.

(6) The undertaking, the relevant local authority or any other organisation responsible for the organisation of emergency response or protective measures shall provide radiological monitoring and medical surveillance for those involved in the taking of the measures, as appropriate.

(7) The undertaking shall ensure that when a radiological emergency occurs the population actually affected by the emergency is informed without delay of the factors of the emergency, of the steps to be taken and, as appropriate, the health protection measures applicable to it.

(8) The information supplied pursuant to paragraph (7) shall include, where relevant to the type of emergency, the following: –

(a) information on the type of emergency that has occurred and, where possible, its characteristics (for example origin, extent and probable development);

(b) advice on protection, which, depending on the type of emergency, may: –

(i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors,

distribution and use of protective substances, evacuation arrangements;

(ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public; and

(c) announcements recommending cooperation with instructions or requests.

(9) Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm.

Communication and recording of significant events

61. (1) The undertaking shall: –

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

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

(c) immediately notify the Agency of any loss, larceny or other misappropriation of any radiation source held by it.

(2) Where an undertaking suspects or has been informed that an occurrence referred to in paragraph (1) has or may have taken place, it shall immediately make an investigation of the matter and submit a report of the investigation to the Agency as soon as possible.

Emergency occupational exposure

62. (1)(a) The Agency shall establish reference levels for emergency occupational exposures. Such reference levels shall apply to emergency workers or other persons involved in taking response actions or protective measures in an emergency, and: –

(i) remain, where possible, below the value of dose limits laid down in Regulation 23; and

(ii) in general, be below an effective dose of 100 mSv where the condition set out in clause (i) is not feasible.

(b) The Agency shall prepare and make available guidelines with regard to reference levels for emergency occupational exposure established under subparagraph (a) having regard to Schedule 1.

(c) The Agency shall prepare guidelines on the training and protection arrangements to be provided to emergency workers who were not pre-designated in the emergency response plan and any volunteers involved in response to an emergency.

(2) In preparing such guidelines, the Agency shall take account of the technical obligations and health risks associated with the emergency response or protective measures concerned.

(3) An exposure of a person referred to in paragraph (1) to a dose in excess of the limits established under that paragraph, but not exceeding 500mSv, may be permitted in exceptional circumstances to save human lives, prevent severe radiation–induced health effects, or prevent catastrophic conditions, where the person has been clearly and comprehensively informed of the associated health risks of such an action and the available protection measures in advance of agreeing voluntarily to undertake such an action.

Prior information and training for emergency workers

63. (1) The employer, undertaking or organisation responsible for the protection of emergency workers in an emergency exposure situation shall ensure that emergency workers are: –

(a) identified in the relevant emergency response plan;

(b) given adequate and regularly updated information on their role in the response, taking into account the range of potential emergencies;

(c) advised on potential health risks and any precautionary measures to be taken in such an event;

(d) provided appropriate training including practical exercises, where appropriate;

(e) provided with supplementary information to ensure their safety should an emergency occur, having regard to the specific circumstances of the emergency; and

(f) provided with radiological and medical surveillance, as appropriate.

Part 8 – NATURALLY OCCURRING RADIATION

National Radon Control Strategy

64. (1) The Minister shall establish and maintain a National Radon Control Strategy aimed at minimising exposure to radon which shall include the following elements: –

(a) measures to promote the identification of dwellings with radon concentrations above the national reference level established by the Agency, pursuant to Regulation 65, as measured in accordance with guidelines as may be issued by the Agency;

(b) where dwellings with radon concentrations above the national reference level are identified, the provision of information aimed at encouraging remedial work to reduce those levels; and

(c) local and national information on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations.

(2) The National Radon Control Strategy shall take into account the issues set out in Schedule 14 and be updated on a regular basis.

(3) The National Radon Control Strategy shall include provisions to identify high radon areas.

Indoor exposure to radon in domestic dwellings

65. The Agency shall establish a Reference Level for indoor radon concentrations in domestic dwellings. The reference level for the annual average activity concentration in air shall not be higher than 300 Bq/m^3.

Radon in workplaces

66. (1) The national reference level for indoor radon concentrations in workplaces is hereby established as an annual average activity concentration in air of 300 Bq/m^3. The Agency shall prepare guidelines for employers on the application of this reference level.

(2) An employer or self-employed person who is responsible for a workplace shall measure the indoor radon concentrations where the workplace is: –

(a) underground, including mines and show caves;

(b) on ground floor or basement level in high radon areas; or

(c) identified by the Agency as being liable to have radon concentrations in excess of the national reference level.

(3) The measurements pursuant to paragraph (2) shall be carried out in accordance with guidelines issued by the Agency.

(4) If the result of any of the radon measurements referred to in paragraph (2) exceeds the national reference level, the employer or self-employed person, shall either take remedial measures to reduce the radon concentrations to below the national reference level or immediately implement the measures set out in in paragraph (6).

(5) If within 12 months of completion of the measurements made pursuant to paragraph (2), the remedial measures referred to in paragraph (4) do not reduce the radon concentrations to below the national reference level the employer or self-employed person shall without delay implement the measures referred to in paragraph (6).

(6) Where having regard to paragraphs (4) and (5) the radon concentrations remain above the national reference level, the employer or self-employed person shall: –

(a) notify the Agency in accordance with Regulation 8;

(b) assess the dose or corresponding time-integrated radon exposure to workers taking into account guidelines as may be issued by the Agency; and

(c) keep this under review taking into account guidelines as may be issued by the Agency.

(7) Where on the basis of the assessment referred to in paragraph 6(b) it is shown that workers are liable to receive an exposure in excess of 6 mSv per year or the corresponding time-integrated radon concentration, the employer or self-employed person shall apply the relevant requirements of these Regulations in accordance with guidelines as may be issued by the Agency.

Gamma radiation from building materials

67. (1) The national reference level applying to external exposure to gamma radiation emitted by building materials is hereby established as 1 mSv per year.

(2) The Agency shall identify building materials that, in terms of the emitted gamma radiation, may be of concern from a radiation protection point of view. The identification of such building materials shall: –

(a) take account of the materials listed in Schedule 10; and

(b) include a determination of the activity concentrations of the radionuclides specified in Schedule 8.

(3) The Agency shall advise the Minister for Housing, Planning and Local Government of building materials that it identifies as being of concern from a radiation protection point of view.

(4) For the building materials referred to in paragraph (3) the Minister for Housing, Planning and Local Government shall decide on appropriate measures, which may include specific requirements in relevant building codes or restrictions on the envisaged use of such materials, taking into account the provisions of Regulation (EU) No 305/2011[10].

Identification of practices involving naturally-occurring radioactive material

68. (1) The Agency may direct an undertaking, carrying out a practice in any industrial sector identified by the Agency, taking into account the sectors listed in Schedule 6, to investigate the extent of exposure of workers or members of the public to naturally-occurring radioactive material.

(2) The results of the investigation referred to in paragraph (1) shall be submitted to the Agency in accordance with guidelines as may be issued by the Agency.

[10] OJ L 88, 4.4.2011, p. 5–43

Part 9 – CONTROL OF RADIOACTIVE SOURCES

Control of radioactive sources and radiation generators

69. (1) This Regulation applies to practices only.

(2) The undertaking shall: –

(a) when acquiring equipment containing radioactive sources or a radiation generator ensure that it is provided with adequate information about its potential radiological hazards and its proper use, testing and maintenance, and with a demonstration that the design permits to restrict exposures to a level that is as low as reasonably achievable;

(b) maintain an up to date inventory of the locations and quantities of sealed and unsealed radioactive sources and radiation generators to which a licence or registration granted to it in accordance with these Regulations applies, and of the dates and method of transfer or recycling or disposal;

(c) if it has in its possession, handles or deals with unsealed radioactive sources maintain records of the quantities and locations of all unsealed radioactive sources used by it;

(d) ensure that the inventory referred to in subparagraph (b) and the records referred to in subparagraph (c) are readily available for inspection at all reasonable times by the Agency;

(e) when required by the Agency, provide to the Agency copies of the inventory referred to in subparagraph (b) and the records referred to in subparagraph (c);

(f) place controls on commodities incorporating radionuclides from the contaminated area;

(g) give consideration of the need to ensure that the form, scale and duration of all protective measures in the strategy are optimised; and

(h) retain the inventory referred to in subparagraph (b) for at least 2 years from the date of transfer or disposal of the items listed in it or, if those items are transferred or disposed of on different dates, the last date on which such an item is transferred or disposed of.

(3) The undertaking shall ensure that: –

(a) sealed and unsealed radioactive sources and radiation generators are clearly labelled as such at all times;

(b) when not in use, sealed and unsealed radioactive sources are segregated from non-radioactive substances and kept in secure and safe storage in accordance with guidelines issued by the Agency; and

(c) for sealed sources, adequate arrangements have been made for the safe and secure management and control of sources, including when they become disused sources. These arrangements shall provide for: –

(i) a repatriation agreement with the supplier or manufacturer; or

(ii) storage in a radioactive waste management facility.

(4) The undertaking shall take whatever steps are appropriate to prevent leakage of any radioactive substance or material from its container or other measures for that protection as far as are practicable.

(5) The undertaking shall ensure, in the case of radioactive sources that: –

(a) suitable tests are carried out to detect leakage of any radioactive substance or material from its container at least once every 2 years or more frequently if recommended by the manufacturer or supplier or if the Agency directs it to do so;

(b) in the case of suspected damage to any container or other protection, a leakage test is undertaken immediately;

(c) if the removed activity in subparagraph (a) and (b) is in excess of 200 Bq, use of the radioactive source shall be discontinued forthwith, and advice and guidance shall be sought from a radiation protection adviser;

(d) a suitable record of every test is made and retained until such time as the radioactive source involved has been disposed of or a further record is made in respect of that radioactive source and that such records are available for inspection by the Agency.

(6) The undertaking shall notify, in each year, the relevant chief fire officer of the location, nature and amount of all radioactive sources held by it.

Requirements for control of high-activity sealed sources

70. The Agency shall ensure, prior to granting a licence for a practice involving a high-activity sealed source, that: –

(a) adequate arrangements have been made for the safe and secure management and control of sources, including when they become disused sources. These arrangements shall provide for: –

(i) a repatriation agreement with the supplier or manufacturer; or

(ii) storage in a radioactive waste management facility.

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

Specific requirements for licensing of high-activity sealed sources

71. The Agency shall ensure that, as a minimum, conditions covering the following areas are specified in a licence for a practice involving a high-activity sealed source: –

(a) responsibilities;

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

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

(d) requirements for emergency procedures and communication links;

(e) work procedures to be followed;

(f) maintenance of equipment, sources and containers; and

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

Record keeping by the undertaking

72. (1) An undertaking responsible for high-activity sealed sources shall keep records of all high-activity sealed sources under its responsibility, including details of their location and transfer. The records shall include the information set out in Schedule 11.

(2) An undertaking responsible for high-activity sealed sources shall provide the Agency with the information contained in the records referred to in paragraph (1), in a format specified by the Agency: –

(a) at the time of the establishment of such record, which shall be as soon as reasonably practicable after the source is acquired;

(b) at intervals, determined by the Agency, of not more than 12 months thereafter;

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

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

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

(f) whenever so requested by the Agency.

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

Record keeping by the competent authority

73. The Agency shall keep records of any undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. These records shall include the radionuclide involved, the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The Agency shall keep the records up to date, taking transfers of the sources and other factors into account.

Control of high-activity sealed sources

74. (1) An undertaking carrying out activities involving high-activity sealed sources shall comply with the requirements set out in Schedule 12.

(2) The manufacturer, supplier, and undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Schedule 13.

Metal Contamination in recycling installations

75. (1) A metal scrap recycling installation shall promptly inform the Agency if it suspects or has knowledge of any melting of, or other metallurgical operation, on an orphan source and shall ensure that the contaminated materials are not used, placed on the market or disposed of without the approval of the Agency.

(2) The installations referred to in paragraph (1) shall ensure that relevant workers in their installation are: –

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

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

(c) informed of and trained in the actions to be taken on site, in accordance with guidelines issued by the Agency, in the event of the detection or suspected detection of a source.

Detection of Orphan Sources

76. (1) The Agency shall inform installations where orphan sources are most likely to be found or processed, including: large metal scrap yards, major metal scrap recycling installations, and significant nodal transit points of the possibility that they may be confronted with a source.

(2) The Agency shall make arrangements for: –

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

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

(c) the provision of specialised technical advice and assistance to persons who suspect the presence of an orphan source and are not normally involved in operations subject to radiation protection requirements.

Recovery and disposal of orphan sources

77. The intervention costs associated with the recovery, management, control and disposal of orphan sources shall, in the first instance, be borne by the person in possession of the source, if identified. The Minister shall make reasonable provision for funds for the recovery and disposal of orphan sources where a responsible person cannot be identified.

Part 10 – SERVICES AND EXPERTS

Recognition of Dosimetry Services

78. (1) The Agency may, by a certificate in writing, approve a dosimetry service for the purpose of these Regulations.

(2) A certificate made pursuant to paragraph (1) may be made subject to conditions and may be amended or revoked by the Agency. These conditions may specify the period of time a certificate is to remain in force.

(3) An application for approval as a dosimetry service shall be made to the Agency in such format and include such particulars as the Agency may from time to time designate.

(4) The Agency shall maintain a register of services approved by it under paragraph (1).

(5) A dosimetry service shall not do any act in pursuance of these Regulations unless it is approved by the Agency in accordance with paragraph (1).

Radiation Protection Advisers

79. (1) The Agency shall: –

(a) establish criteria for the approval of radiation protection advisers;

(b) establish and maintain a register containing the names of persons standing approved by the Agency as persons who may be consulted as radiation protection advisers for a specified period as may be determined by the Agency; and

(c) remove the name of a person from the register where the Agency is of the view that such person no longer meets the criteria established under subparagraph (a).

(2) (a) The Agency may approve persons for that purpose whether in relation to practices generally or a particular type of practice and the register referred to in subparagraph (1)(b) shall be divided into parts corresponding to those types of practice and the name of each person standing approved under subparagraph (1)(b) shall be entered in the appropriate part of that register accordingly;

(b) The Agency may amend the particulars relating to the types of practice in respect of which a person stands approved under paragraph (a).

(3) For the purposes of subparagraph (1)(a), the Agency may, after consultation with such professional bodies as it considers appropriate, determine and publish educational, training or other requirements (whether relating to qualifications, types of practice, work activities or otherwise) to be met before it approves a person under paragraph (2).

Radiation Protection Officers

80. (1) The Agency shall set out the minimum training requirements for radiation protection officers.

(2) The Agency shall determine in which practices the designation of a radiation protection officer is necessary to supervise or to perform radiation protection tasks within an undertaking.

(3) The Agency may require employers of outside workers to designate a radiation protection officer as necessary to supervise or perform relevant radiation protection tasks as they relate to the protection of their workers.

Part 11 - ENFORCEMENT

Inspections

81. (1) The Agency shall establish and maintain a system or systems of inspection to enforce the provisions adopted pursuant to these Regulations and to initiate surveillance and corrective action where necessary. This shall include an inspection programme taking into account the potential magnitude and nature of the hazard associated with practices, a general assessment of radiation protection issues in the practices, and the state of compliance with these Regulations.

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

(3) The Agency may make the outlines of the inspection programmes and the main findings from their implementation available to the public.

(4) The Agency shall put mechanisms in place for the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections, reported incidents, accidents and related findings.

Enforcement Notices

82. (1) If an inspector is of the opinion that a person or undertaking has contravened or is contravening a provision(s) of these Regulations, the inspector may serve on that person or undertaking a notice in writing (in these Regulations referred to as "an enforcement notice") requiring him or her to do or not to do such things as are specified in the notice for the purposes of ensuring compliance with the provision(s) concerned to mitigate or to remedy any effects of the contravention concerned.

(2) An enforcement notice shall: –

(a) be signed by the inspector issuing it;

(b) identify the provision(s) and requirement(s) of these Regulations with which there has not been compliance;

(c) identify the corrective actions to be taken to mitigate or remedy any effects of the contravention concerned;

(d) where appropriate, direct the person or undertaking on whom the enforcement notice is served to cease the carrying on of the practice, human activity or work activity concerned until such time as all appropriate measures, including corrective measures, have been taken to bring the practice or work activity into conformity with these Regulations;

(e) give a time period, commensurate with the nature of the risk, within which the person or undertaking on whom the enforcement notice is served must take the corrective actions identified in subparagraph (c); and

(f) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal may be brought.

(3) (a) Where an inspector issues an enforcement notice under this Regulation, it shall be addressed to the person or undertaking concerned and, as soon as practicable, be sent or given in any of the following ways: –

(i) by delivering it to the person or undertaking;

(ii) by leaving it at the address at which the person or undertaking ordinarily carries on business;

(iii) by sending it by pre-paid registered post addressed to the person or undertaking at the address at which the person or undertaking ordinarily carries on business;

(iv) if an address for the service of enforcement notices has been furnished by the person or undertaking to the Inspector, by leaving it at, or sending it by pre-paid registered post to, that address; or

(v) in any case where the inspector considers that the immediate giving of the direction or notice is required, by sending it, by means of a facsimile machine or by electronic mail, to a device or facility for the reception of facsimiles or electronic mail located at the address at which the person or undertaking ordinarily carries on business or, if an address for the service of notices has been furnished by the person or undertaking, that address, but only if: –

(I) the sender's facsimile machine generates a message confirming successful delivery of the total number of pages of the direction or notice; or

(II) the recipient's facility for the reception of electronic mail generates a message confirming receipt of the electronic mail;

and it is also given in one of the other ways mentioned in clauses (i) to (iv).

(b) In subparagraph (a), a company within the meaning of the Companies Acts is deemed to be ordinarily resident at its registered office and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.

(4) An enforcement notice shall take effect: –

(a) where no appeal is taken, on the date it is served in accordance with paragraph (3); or

(b) where an appeal is taken, on the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn or on the date it is served in accordance with paragraph (3), whichever is the later.

(5) A person or undertaking on which an enforcement notice is served may, within the period of 21 days beginning on the day on which the notice is served on him or her, appeal to the appropriate judge of the Circuit Court against the notice.

(6) On the hearing of an appeal under paragraph (5) the court may, as it thinks proper: –

(a) confirm the notice unconditionally;

(b) make such modifications to the notice as it considers appropriate and confirm this notice, as so modified; or

(c) cancel the notice.

(7) An inspector may cancel an enforcement notice served under this Regulation (other than such a notice that has been confirmed under paragraph (6)).

(8) An inspector may apply to the Circuit Court for an order cancelling an enforcement notice that has been confirmed under paragraph (6) and the court shall, on the hearing of the application, unless it sees good reason to the contrary, grant such an order.

(9) Where an enforcement notice has been served and is in effect and the person or undertaking concerned has not complied with the notice, the Circuit Court may, on the application of the inspector, by order direct the person or undertaking concerned to comply with the notice.

(10) An application to the Circuit Court under paragraph (9) shall be by motion and the Circuit Court when considering the matter may make such interim or interlocutory order (if any) as it considers appropriate.

(11) The order by which an application under paragraph (9) is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

(12) An application for an order under this Regulation may be made whether or not there has been a prosecution for an offence under these Regulations in relation to the practice, human activity or work activity concerned, and shall not prejudice the initiation of a prosecution for an offence under these Regulations in relation to the practice, human activity or work activity concerned.

Part 12 – REVOCATION OF LEGISLATION

Revocations

83. (1) The following instruments are hereby revoked: –

(a) European Communities (Radiological Emergency Warning to Public) Regulations 1993 (S.I. No. 209 of 1993);

(b) Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000);

(c) Radiological Protection Act 1991 (Control of High-Activity Sealed Radioactive Sources) Order 2005 (S.I. No. 875 of 2005); and

(d) Radiological Protection Act 1991 (Responsible and Safe Management of Radioactive Waste) Order 2013 (S.I. No. 320 of 2013).

(2) References in other enactments to the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) shall be construed as references to these Regulations.

Part 13 - TRANSITIONAL PROVISIONS

Licences

84. Notwithstanding the revocation of the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) by these Regulations, a licence granted under that Order which is in force immediately before the commencement of these Regulations shall remain in force for the unexpired period of the licence as if granted by the Agency pursuant to these Regulations, or the licence is amended or revoked by the Agency pursuant to its powers under the Principal Act and these Regulations.

Applications for Licences

85. Notwithstanding the revocation of the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) by these Regulations, an

application for a licence, or the renewal of a licence, made to the Agency pursuant to that Order immediately before the commencement of these Regulations shall be regarded as an application for authorisation under these Regulations.

Dosimetry Services

86. Notwithstanding the revocation of the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) by these Regulations, an approval of a dosimetry service under Article 24 of that Order which is in force immediately before the commencement of these Regulations shall be deemed to constitute an approval granted under Regulation 78 of these Regulations until the date specified in such existing approval as the date of its expiry or 31 December 2019, whichever date is the earlier.

Radiation Protection Advisers

87. Notwithstanding the revocation of the Radiological Protection Act 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) by these Regulations and without prejudice to Regulation 79, a person approved by the Agency to act as a radiation protection adviser under that order and entered in the radiation protection adviser register maintained by the Agency pursuant to the Order will be deemed so approved pursuant to these Regulations and included in the radiation protection adviser register for the purposes of these Regulations.

SCHEDULE 1

Reference levels for public exposure as referred to in Regulations 21, 56 and 62

1. Without prejudice to reference levels set for equivalent doses, reference levels expressed in effective doses shall be set in the range of 1 to 20 mSv per year for existing exposure situations and 20 to 100 mSv (acute or annual) for emergency exposure situations.

2. In specific situations, a reference level below ranges referred to in point 1 may be considered, in particular: –

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

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

3. For the transition from an emergency exposure situation to an existing exposure situation, appropriate reference levels shall be set, in particular upon the termination of long-term countermeasures such as relocation.

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

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

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

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

SCHEDULE 2

Radiation and tissue weighting factors

A. ***Radiation weighting factors***

Radiation type	w_R
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, $E_n < 1$ MeV	$2{,}5 + 18{,}2\, e^{-[\ln(En)]^2/6}$
Neutrons, 1 MeV $\leq E_n \leq$ 50 MeV	$5{,}0 + 17{,}0\, e^{-[\ln(2\,En)]^2/6}$
Neutrons, $E_n > 50$ MeV	$2{,}5 + 3{,}25\, e^{-[\ln(0{,}04\,En)]^2/6}$
Note:All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).	

B. ***Tissue weighting factors***

Tissue	w_T
Bone-marrow (red)	0,12
Colon	0,12
Lung	0,12
Stomach	0,12
Breast	0,12
Remainder tissues [1]	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

[1] 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).

SCHEDULE 3

Activity values defining high-activity sealed sources

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

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

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

SCHEDULE 4

Justification of new classes or types of practices involving consumer products as referred to in Regulation 6

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

(1) intended use of the product;

(2) technical characteristics of the product;

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

(4) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0,1 m from any accessible surface;

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

B. The Agency shall examine that information and in particular assess whether: –

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

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

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

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

SCHEDULE 5

Indicative list of practices involving non-medical imaging exposure as referred to in Regulation 16

Practices using medical radiological equipment: –

1. Radiological health assessment for employment purposes;
2. Radiological health assessment for immigration purposes;
3. Radiological health assessment for insurance purposes;
4. Radiological evaluation of the physical development of children and adolescents with a view to a career in sports, dancing, etc.;
5. Radiological age assessment;
6. Use of ionising radiation for the identification of concealed objects within the human body.

Practices not using medical radiological equipment: –

1. Use of ionising radiation for detection of concealed objects on or attached to the human body;
2. Use of ionising radiation for detection of concealed humans as part of cargo screening;
3. Practices involving the use of ionising radiation for legal or security purposes.

SCHEDULE 6

List of industrial sectors involving naturally-occurring radioactive material as referred to in Regulation 68

When applying Regulation 68 the following list of industrial sectors involving naturally-occurring radioactive material, including research and relevant secondary processes, shall be taken into account: –

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

SCHEDULE 7

Exemption and clearance criteria as referred to in Regulations 8, 9 and 19

1. Exemption

Practices may be exempted from notification either directly, on the basis of compliance with exemption levels (activity values (in Bq) or activity concentration values (in kBq kg^{-1})) laid down in Part 2, or on the basis of higher values that, for specific applications, are established by the Agency, satisfying the general exemption and clearance criteria set out in Part 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 Part 3.

2. Exemption and clearance levels

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

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

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

(d) For mixtures of artificial radionuclides, the weighted sum of nuclide-specific activities or concentrations (for various radionuclides contained in the same matrix) divided by the corresponding exemption value shall be less than unity. Where appropriate, this condition can be verified on the basis of best estimates of the composition of the radionuclide mix. The values in Table A, Part 2, apply individually to each parent nuclide. Some elements in the decay chain, e.g. Po-210 or Pb-210, may warrant the use of higher values taking Community guidance into account;

(e) The values in Table A, Part 2, may not be used to exempt the incorporation into building materials of residues from industries processing naturally-occurring radioactive material. For this purpose, compliance with the provisions of Regulation 67 shall be verified. The values laid down in Table B, column 3, apply to the total inventory of radioactive substances held by a person or undertaking as part of a specific practice at any point in time. However, the 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 Part 3 are satisfied.

3. General exemption and clearance criteria

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

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

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

(iii) the practice is inherently safe.

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

(c) Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1, or Table B, are deemed to comply with criterion (i) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water;

(d) In the case of moderate amounts of material, as specified by the Agency for specific types of practice, the activity concentration values laid down in Table B, column 2, may be used instead of the values laid down in Table A, Part 1, for the purpose of exemption from authorisation;

(e) For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A or Table B, an assessment shall be made in the light of the general criteria (i) to (iii) above. For compliance with the general criterion (i), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances: –

— For artificial radionuclides: –

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 μSv or less in a year.

— For naturally-occurring radionuclides: –

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Member States may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

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

TABLE A

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

TABLE A PART 1

Artificial radionuclides

Radionuclide	Activity concentration ($kBq\ kg^{-1}$)
H-3	100
Be-7	10
C-14	1
F-18	10
Na-22	0,1
Na-24	1
Si-31	1 000
P-32	1 000
P-33	1 000
S-35	100
Cl-36	1
Cl-38	10
K-42	100
K-43	10
Ca-45	100
Ca-47	10
Sc-46	0,1
Sc-47	100
Sc-48	1
V-48	1
Cr-51	100
Mn-51	10
Mn-52	1
Mn-52 m	10
Mn-53	100

Mn-54	0,1
Mn-56	10
Fe-52 [a]	10
Fe-55	1 000
Fe-59	1
Co-55	10
Co-56	0,1
Co-57	1
Co-58	1
Co-58 m	10 000
Co-60	0,1
Co-60 m	1 000
Co-61	100
Co-62 m	10
Ni-59	100
Ni-63	100
Ni-65	10
Cu-64	100
Zn-65	0,1
Zn-69	1 000
Zn-69 m [a]	10
Ga-72	10
Ge-71	10 000
As-73	1 000
As-74	10
As-76	10
As-77	1 000
Se-75	1
Br-82	1
Rb-86	100
Sr-85	1
Sr-85 m	100
Sr-87 m	100
Sr-89	1 000

Sr-90 [a]	1
Sr-91 [a]	10
Sr-92	10
Y-90	1 000
Y-91	100
Y-91 m	100
Y-92	100
Y-93	100
Zr-93	10
Zr-95 [a]	1
Zr-97 [a]	10
Nb-93 m	10
Nb-94	0,1
Nb-95	1
Nb-97 [a]	10
Nb-98	10
Mo-90	10
Mo-93	10
Mo-99 [a]	10
Mo-101 [a]	10
Tc-96	1
Tc-96 m	1 000
Tc-97	10
Tc-97 m	100
Tc-99	1
Tc-99 m	100
Ru-97	10
Ru-103 [a]	1
Ru-105 [a]	10
Ru-106 [a]	0,1
Rh-103 m	10 000
Rh-105	100
Pd-103 [a]	1 000
Pd-109 [a]	100

Ag-105	1
Ag-110 m [a]	0,1
Ag-111	100
Cd-109 [a]	1
Cd-115 [a]	10
Cd-115 m [a]	100
In-111	10
In-113 m	100
In-114 m [a]	10
In-115 m	100
Sn-113 [a]	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125 [a]	0,1
Te-123 m	1
Te-125 m	1 000
Te-127	1 000
Te-127 m [a]	10
Te-129	100
Te-129 m [a]	10
Te-131	100
Te-131 m [a]	10
Te-132 [a]	1
Te-133	10
Te-133 m	10
Te-134	10
I-123	100
I-125	100
I-126	10
I-129	0,01
I-130	10
I-131	10
I-132	10

I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1 000
Cs-132	10
Cs-134	0,1
Cs-134 m	1 000
Cs-135	100
Cs-136	1
Cs-137[a]	0,1
Cs-138	10
Ba-131	10
Ba-140	1
La-140	1
Ce-139	1
Ce-141	100
Ce-143	10
Ce-144	10
Pr-142	100
Pr-143	1 000
Nd-147	100
Nd-149	100
Pm-147	1 000
Pm-149	1 000
Sm-151	1 000
Sm-153	100
Eu-152	0,1
Eu-152 m	100
Eu-154	0,1
Eu-155	1
Gd-153	10
Gd-159	100
Tb-160	1

Dy-165	1 000
Dy-166	100
Ho-166	100
Er-169	1 000
Er-171	100
Tm-170	100
Tm-171	1 000
Yb-175	100
Lu-177	100
Hf-181	1
Ta-182	0,1
W-181	10
W-185	1 000
W-187	10
Re-186	1 000
Re-188	100
Os-185	1
Os-191	100
Os-191 m	1 000
Os-193	100
Ir-190	1
Ir-192	1
Ir-194	100
Pt-191	10
Pt-193 m	1 000
Pt-197	1 000
Pt-197 m	100
Au-198	10
Au-199	100
Hg-197	100
Hg-197 m	100
Hg-203	10
Tl-200	10
Tl-201	100

Tl-202	10
Tl-204	1
Pb-203	10
Bi-206	1
Bi-207	0,1
Po-203	10
Po-205	10
Po-207	10
At-211	1 000
Ra-225	10
Ra-227	100
Th-226	1 000
Th-229	0,1
Pa-230	10
Pa-233	10
U-230	10
U-231[a]	100
U-232[a]	0,1
U-233	1
U-236	10
U-237	100
U-239	100
U-240[a]	100
Np-237[a]	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0,1
Pu-239	0,1
Pu-240	0,1
Pu-241	10

Pu-242	0,1
Pu-243	1 000
Pu-244 [a]	0,1
Am-241	0,1
Am-242	1 000
Am-242 m [a]	0,1
Am-243 [a]	0,1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0,1
Cm-246	0,1
Cm-247 [a]	0,1
Cm-248	0,1
Bk-249	100
Cf-246	1 000
Cf-248	1
Cf-249	0,1
Cf-250	1
Cf-251	0,1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254 [a]	0,1
Es-254 m [a]	10
Fm-254	10 000
Fm-255	100

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

Parent radionuclide	**Progeny**
Fe-52	Mn-52 m

Zn-69 m	Zn-69
Sr-90	Y-90
Sr-91	Y-91 m
Zr-95	Nb-95
Zr-97	Nb-97 m, Nb-97
Nb-97	Nb-97 m
Mo-99	Tc-99 m
Mo-101	Tc-101
Ru-103	Rh-103 m
Ru-105	Rh-105 m
Ru-106	Rh-106
Pd-103	Rh-103 m
Pd-109	Ag-109 m
Ag-110 m	Ag-110
Cd-109	Ag-109 m
Cd-115	In-115 m
Cd-115 m	In-115 m
In-114 m	In-114
Sn-113	In-113 m
Sb-125	Te-125 m
Te-127 m	Te-127
Te-129 m	Te-129
Te-131 m	Te-131
Te132	I-132
Cs-137	Ba-137 m
Ce-144	Pr-144, Pr-144 m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240 m, Np-240
Np237	Pa-233
Pu-244	U-240, Np-240 m, Np-240
Am-242 m	Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250

Es-254 m	Fm-254

For radionuclides not listed in Table A, Part 1 the competent authority shall assign appropriate values for the quantities and concentrations of activity per unit mass where the need arises. Values thus assigned shall be complementary to those in Table A, Part 1.

TABLE A PART 2

Naturally occurring radionuclides

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

Natural radionuclides from the U-238 series	1 kBq kg^{-1}
Natural radionuclides from the Th-232 series	1 kBq kg^{-1}
K-40	10 kBq kg^{-1}

TABLE B

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

Radionuclide	**Activity concentration (kBq kg^{-1})**	**Activity (Bq)**
H-3	1×10^6	1×10^9
Be-7	1×10^3	1×10^7
C-14	1×10^4	1×10^7
O-15	1×10^2	1×10^9
F-18	1×10^1	1×10^6
Na-22	1×10^1	1×10^6
Na-24	1×10^1	1×10^5
Si-31	1×10^3	1×10^6
P-32	1×10^3	1×10^5
P-33	1×10^5	1×10^8
S-35	1×10^5	1×10^8
Cl-36	1×10^4	1×10^6
Cl-38	1×10^1	1×10^5
Ar-37	1×10^6	1×10^8
Ar-41	1×10^2	1×10^9
K-40[1]	1×10^2	1×10^6
K-42	1×10^2	1×10^6

K-43	1×10^{1}	1×10^{6}
Ca-45	1×10^{4}	1×10^{7}
Ca-47	1×10^{1}	1×10^{6}
Sc-46	1×10^{1}	1×10^{6}
Sc-47	1×10^{2}	1×10^{6}
Sc-48	1×10^{1}	1×10^{5}
V-48	1×10^{1}	1×10^{5}
Cr-51	1×10^{3}	1×10^{7}
Mn-51	1×10^{1}	1×10^{5}
Mn-52	1×10^{1}	1×10^{5}
Mn-52 m	1×10^{1}	1×10^{5}
Mn-53	1×10^{4}	1×10^{9}
Mn-54	1×10^{1}	1×10^{6}
Mn-56	1×10^{1}	1×10^{5}
Fe-52	1×10^{1}	1×10^{6}
Fe-55	1×10^{4}	1×10^{6}
Fe-59	1×10^{1}	1×10^{6}
Co-55	1×10^{1}	1×10^{6}
Co-56	1×10^{1}	1×10^{5}
Co-57	1×10^{2}	1×10^{6}
Co-58	1×10^{1}	1×10^{6}
Co-58 m	1×10^{4}	1×10^{7}
Co-60	1×10^{1}	1×10^{5}
Co-60 m	1×10^{3}	1×10^{6}
Co-61	1×10^{2}	1×10^{6}
Co-62 m	1×10^{1}	1×10^{5}
Ni-59	1×10^{4}	1×10^{8}
Ni-63	1×10^{5}	1×10^{8}
Ni-65	1×10^{1}	1×10^{6}
Cu-64	1×10^{2}	1×10^{6}
Zn-65	1×10^{1}	1×10^{6}
Zn-69	1×10^{4}	1×10^{6}
Zn-69 m	1×10^{2}	1×10^{6}
Ga-72	1×10^{1}	1×10^{5}

Ge-71	1×10^{4}	1×10^{8}
As-73	1×10^{3}	1×10^{7}
As-74	1×10^{1}	1×10^{6}
As-76	1×10^{2}	1×10^{5}
As-77	1×10^{3}	1×10^{6}
Se-75	1×10^{2}	1×10^{6}
Br-82	1×10^{1}	1×10^{6}
Kr-74	1×10^{2}	1×10^{9}
Kr-76	1×10^{2}	1×10^{9}
Kr-77	1×10^{2}	1×10^{9}
Kr-79	1×10^{3}	1×10^{5}
Kr-81	1×10^{4}	1×10^{7}
Kr-83 m	1×10^{5}	1×10^{12}
Kr-85	1×10^{5}	1×10^{4}
Kr-85 m	1×10^{3}	1×10^{10}
Kr-87	1×10^{2}	1×10^{9}
Kr-88	1×10^{2}	1×10^{9}
Rb-86	1×10^{2}	1×10^{5}
Sr-85	1×10^{2}	1×10^{6}
Sr-85 m	1×10^{2}	1×10^{7}
Sr-87 m	1×10^{2}	1×10^{6}
Sr-89	1×10^{3}	1×10^{6}
Sr-90 [b]	1×10^{2}	1×10^{4}
Sr-91	1×10^{1}	1×10^{5}
Sr-92	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}
Y-91	1×10^{3}	1×10^{6}
Y-91 m	1×10^{2}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}
Y-93	1×10^{2}	1×10^{5}
Zr-93 [b]	1×10^{3}	1×10^{7}
Zr-95	1×10^{1}	1×10^{6}
Zr-97 [b]	1×10^{1}	1×10^{5}
Nb-93 m	1×10^{4}	1×10^{7}

Nb-94	1×10^{1}	1×10^{6}
Nb-95	1×10^{1}	1×10^{6}
Nb-97	1×10^{1}	1×10^{6}
Nb-98	1×10^{1}	1×10^{5}
Mo-90	1×10^{1}	1×10^{6}
Mo-93	1×10^{3}	1×10^{8}
Mo-99	1×10^{2}	1×10^{6}
Mo-101	1×10^{1}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}
Tc-96 m	1×10^{3}	1×10^{7}
Tc-97	1×10^{3}	1×10^{8}
Tc-97 m	1×10^{3}	1×10^{7}
Tc-99	1×10^{4}	1×10^{7}
Tc-99 m	1×10^{2}	1×10^{7}
Ru-97	1×10^{2}	1×10^{7}
Ru-103	1×10^{2}	1×10^{6}
Ru-105	1×10^{1}	1×10^{6}
Ru-106 [b]	1×10^{2}	1×10^{5}
Rh-103 m	1×10^{4}	1×10^{8}
Rh-105	1×10^{2}	1×10^{7}
Pd-103	1×10^{3}	1×10^{8}
Pd-109	1×10^{3}	1×10^{6}
Ag-105	1×10^{2}	1×10^{6}
Ag-108 m	1×10^{1}	1×10^{6}
Ag-110 m	1×10^{1}	1×10^{6}
Ag-111	1×10^{3}	1×10^{6}
Cd-109	1×10^{4}	1×10^{6}
Cd-115	1×10^{2}	1×10^{6}
Cd-115 m	1×10^{3}	1×10^{6}
In-111	1×10^{2}	1×10^{6}
In-113 m	1×10^{2}	1×10^{6}
In-114 m	1×10^{2}	1×10^{6}
In-115 m	1×10^{2}	1×10^{6}
Sn-113	1×10^{3}	1×10^{7}

Sn-125	1×10^{2}	1×10^{5}
Sb-122	1×10^{2}	1×10^{4}
Sb-124	1×10^{1}	1×10^{6}
Sb-125	1×10^{2}	1×10^{6}
Te-123 m	1×10^{2}	1×10^{7}
Te-125 m	1×10^{3}	1×10^{7}
Te-127	1×10^{3}	1×10^{6}
Te-127 m	1×10^{3}	1×10^{7}
Te-129	1×10^{2}	1×10^{6}
Te-129 m	1×10^{3}	1×10^{6}
Te-131	1×10^{2}	1×10^{5}
Te-131 m	1×10^{1}	1×10^{6}
Te-132	1×10^{2}	1×10^{7}
Te-133	1×10^{1}	1×10^{5}
Te-133 m	1×10^{1}	1×10^{5}
Te-134	1×10^{1}	1×10^{6}
I-123	1×10^{2}	1×10^{7}
I-125	1×10^{3}	1×10^{6}
I-126	1×10^{2}	1×10^{6}
I-129	1×10^{2}	1×10^{5}
I-130	1×10^{1}	1×10^{6}
I-131	1×10^{2}	1×10^{6}
I-132	1×10^{1}	1×10^{5}
I-133	1×10^{1}	1×10^{6}
I-134	1×10^{1}	1×10^{5}
I-135	1×10^{1}	1×10^{6}
Xe-131 m	1×10^{4}	1×10^{4}
Xe-133	1×10^{3}	1×10^{4}
Xe-135	1×10^{3}	1×10^{10}
Cs-129	1×10^{2}	1×10^{5}
Cs-131	1×10^{3}	1×10^{6}
Cs-132	1×10^{1}	1×10^{5}
Cs-134 m	1×10^{3}	1×10^{5}
Cs-134	1×10^{1}	1×10^{4}

Cs-135	1×10^{4}	1×10^{7}
Cs-136	1×10^{1}	1×10^{5}
Cs-137 [b]	1×10^{1}	1×10^{4}
Cs-138	1×10^{1}	1×10^{4}
Ba-131	1×10^{2}	1×10^{6}
Ba-140 [b]	1×10^{1}	1×10^{5}
La-140	1×10^{1}	1×10^{5}
Ce-139	1×10^{2}	1×10^{6}
Ce-141	1×10^{2}	1×10^{7}
Ce-143	1×10^{2}	1×10^{6}
Ce-144 [b]	1×10^{2}	1×10^{5}
Pr-142	1×10^{2}	1×10^{5}
Pr-143	1×10^{4}	1×10^{6}
Nd-147	1×10^{2}	1×10^{6}
Nd-149	1×10^{2}	1×10^{6}
Pm-147	1×10^{4}	1×10^{7}
Pm-149	1×10^{3}	1×10^{6}
Sm-151	1×10^{4}	1×10^{8}
Sm-153	1×10^{2}	1×10^{6}
Eu-152	1×10^{1}	1×10^{6}
Eu-152 m	1×10^{2}	1×10^{6}
Eu-154	1×10^{1}	1×10^{6}
Eu-155	1×10^{2}	1×10^{7}
Gd-153	1×10^{2}	1×10^{7}
Gd-159	1×10^{3}	1×10^{6}
Tb-160	1×10^{1}	1×10^{6}
Dy-165	1×10^{3}	1×10^{6}
Dy-166	1×10^{3}	1×10^{6}
Ho-166	1×10^{3}	1×10^{5}
Er-169	1×10^{4}	1×10^{7}
Er-171	1×10^{2}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}
Yb-175	1×10^{3}	1×10^{7}

Lu-177	1×10^{3}	1×10^{7}
Hf-181	1×10^{1}	1×10^{6}
Ta-182	1×10^{1}	1×10^{4}
W-181	1×10^{3}	1×10^{7}
W-185	1×10^{4}	1×10^{7}
W-187	1×10^{2}	1×10^{6}
Re-186	1×10^{3}	1×10^{6}
Re-188	1×10^{2}	1×10^{5}
Os-185	1×10^{1}	1×10^{6}
Os-191	1×10^{2}	1×10^{7}
Os-191 m	1×10^{3}	1×10^{7}
Os-193	1×10^{2}	1×10^{6}
Ir-190	1×10^{1}	1×10^{6}
Ir-192	1×10^{1}	1×10^{4}
Ir-194	1×10^{2}	1×10^{5}
Pt-191	1×10^{2}	1×10^{6}
Pt-193 m	1×10^{3}	1×10^{7}
Pt-197	1×10^{3}	1×10^{6}
Pt-197 m	1×10^{2}	1×10^{6}
Au-198	1×10^{2}	1×10^{6}
Au-199	1×10^{2}	1×10^{6}
Hg-197	1×10^{2}	1×10^{7}
Hg-197 m	1×10^{2}	1×10^{6}
Hg-203	1×10^{2}	1×10^{5}
Tl-200	1×10^{1}	1×10^{6}
Tl-201	1×10^{2}	1×10^{6}
Tl-202	1×10^{2}	1×10^{6}
Tl-204	1×10^{4}	1×10^{4}
Pb-203	1×10^{2}	1×10^{6}
Pb-210 [b]	1×10^{1}	1×10^{4}
Pb-212 [b]	1×10^{1}	1×10^{5}
Bi-206	1×10^{1}	1×10^{5}
Bi-207	1×10^{1}	1×10^{6}
Bi-210	1×10^{3}	1×10^{6}

Bi-212 [b]	1×10^{1}	1×10^{5}
Po-203	1×10^{1}	1×10^{6}
Po-205	1×10^{1}	1×10^{6}
Po-207	1×10^{1}	1×10^{6}
Po-210	1×10^{1}	1×10^{4}
At-211	1×10^{3}	1×10^{7}
Rn-220 [b]	1×10^{4}	1×10^{7}
Rn-222 [b]	1×10^{1}	1×10^{8}
Ra-223 [b]	1×10^{2}	1×10^{5}
Ra-224 [b]	1×10^{1}	1×10^{5}
Ra-225	1×10^{2}	1×10^{5}
Ra-226 [b]	1×10^{1}	1×10^{4}
Ra-227	1×10^{2}	1×10^{6}
Ra-228 [b]	1×10^{1}	1×10^{5}
Ac-228	1×10^{1}	1×10^{6}
Th-226 [b]	1×10^{3}	1×10^{7}
Th-227	1×10^{1}	1×10^{4}
Th-228 [b]	1×10^{0}	1×10^{4}
Th-229 [b]	1×10^{0}	1×10^{3}
Th-230	1×10^{0}	1×10^{4}
Th-231	1×10^{3}	1×10^{7}
Th-234 [b]	1×10^{3}	1×10^{5}
Pa-230	1×10^{1}	1×10^{6}
Pa-231	1×10^{0}	1×10^{3}
Pa-233	1×10^{2}	1×10^{7}
U-230	1×10^{1}	1×10^{5}
U-231	1×10^{2}	1×10^{7}
U-232 [b]	1×10^{0}	1×10^{3}
U-233	1×10^{1}	1×10^{4}
U-234	1×10^{1}	1×10^{4}
U-235 [b]	1×10^{1}	1×10^{4}
U-236	1×10^{1}	1×10^{4}
U-237	1×10^{2}	1×10^{6}
U-238 [b]	1×10^{1}	1×10^{4}

U-239	1×10^{2}	1×10^{6}
U-240	1×10^{3}	1×10^{7}
U-240 [b]	1×10^{1}	1×10^{6}
Np-237 [b]	1×10^{0}	1×10^{3}
Np-239	1×10^{2}	1×10^{7}
Np-240	1×10^{1}	1×10^{6}
Pu-234	1×10^{2}	1×10^{7}
Pu-235	1×10^{2}	1×10^{7}
Pu-236	1×10^{1}	1×10^{4}
Pu-237	1×10^{3}	1×10^{7}
Pu-238	1×10^{0}	1×10^{4}
Pu-239	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{3}
Pu-241	1×10^{2}	1×10^{5}
Pu-242	1×10^{0}	1×10^{4}
Pu-243	1×10^{3}	1×10^{7}
Pu-244	1×10^{0}	1×10^{4}
Am-241	1×10^{0}	1×10^{4}
Am-242	1×10^{3}	1×10^{6}
Am-242 m [b]	1×10^{0}	1×10^{4}
Am-243 [b]	1×10^{0}	1×10^{3}
Cm-242	1×10^{2}	1×10^{5}
Cm-243	1×10^{0}	1×10^{4}
Cm-244	1×10^{1}	1×10^{4}
Cm-245	1×10^{0}	1×10^{3}
Cm-246	1×10^{0}	1×10^{3}
Cm-247	1×10^{0}	1×10^{4}
Cm-248	1×10^{0}	1×10^{3}
Bk-249	1×10^{3}	1×10^{6}
Cf-246	1×10^{3}	1×10^{6}
Cf-248	1×10^{1}	1×10^{4}
Cf-249	1×10^{0}	1×10^{3}
Cf-250	1×10^{1}	1×10^{4}
Cf-251	1×10^{0}	1×10^{3}

Cf-252	1×10^{1}	1×10^{4}
Cf-253	1×10^{2}	1×10^{5}
Cf-254	1×10^{0}	1×10^{3}
Es-253	1×10^{2}	1×10^{5}
Es-254	1×10^{1}	1×10^{4}
Es-254 m	1×10^{2}	1×10^{6}
Fm-254	1×10^{4}	1×10^{7}
Fm-255	1×10^{3}	1×10^{6}

[1] Potassium salts in quantities less than 1 000 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-93 m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108 m	Ag-108
Cs-137	Ba-137 m
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

Th-234	Pa-234 m
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-234 m
U-240	Np-240 m
Np237	Pa-233
Am-242 m	Am-242
Am-243	Np-239

SCHEDULE 8

Definition and use of the activity concentration index for the gamma radiation emitted by building materials as referred to in Regulation 67

For the purposes of Regulation 67(2), for identified types of building materials, the activity concentrations of primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40 shall be determined.

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

$$I = C_{Ra226}/300\,Bq/kg + C_{Th232}/200\,Bq/kg + C_{K40}/3\,000\,Bq/kg$$

where C_{Ra226}, C_{Th232} and C_{K40} are the activity concentrations in Bq/kg of the corresponding radionuclides in the building material.

The index relates to the gamma radiation dose, in excess of typical outdoor exposure, in a building constructed from a specified building material. The index applies to the building material, not to its constituents except when those constituents are building materials themselves and are separately assessed as such. For application of the index to such constituents, in particular residues from industries processing naturally-occurring radioactive material recycled into building materials, an appropriate partitioning factor needs to be applied. The activity concentration index value of 1 can be used as a conservative screening tool for identifying materials that may cause the reference level laid down in Regulation 67(1) to be exceeded. The calculation of dose needs to take into account other factors such as density, thickness of the material as well as factors relating to the type of building and the intended use of the material (bulk or superficial).

SCHEDULE 9

Data system for individual radiological monitoring as referred to in Regulations 29, 42, 43, 44 and 50

GENERAL PROVISIONS

1. The data system for individual radiological monitoring of exposed workers shall be in the form of a National Dose Register and include the issuance of radiation passbooks for outside workers, and shall comprise the following sections: ─

(a) particulars concerning the worker's identity;

(b) particulars concerning the medical surveillance of the worker;

(c) particulars concerning the undertaking of the worker and, in the case of an outside worker, the employer of the worker; and

(d) the results of the individual monitoring of the exposed worker.

2. The Agency shall take the measures necessary to prevent any forgery or misuse of, or tampering with, the National Dose Register.

A. Data to be included in the National Dose Register

3. Data on the worker's identity shall include the worker's: ─

(a) surname;

(b) first name;

(c) sex;

(d) date of birth;

(e) nationality; and

(f) unique identification number.

4. Data on the undertaking shall include the name, address and unique identification number of the undertaking.

5. Data on the employment of the worker shall include: ─

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

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

(c) the categorisation of the worker in accordance with Regulation 39.

6. The results of the individual monitoring of the exposed worker shall include the official dose record (year; effective dose in mSv; in the event of non-uniform exposure, equivalent doses in the different parts of the body in mSv; and in the event of an intake of radionuclides, the committed effective dose in mSv);

B. Data on outside workers to be supplied via the radiation passbook

1. Before the start of any work activity, the employer of the outside worker shall supply the following data to the undertaking via the radiation passbook: –

(a) data on the employment of the outside worker in accordance with Part A, point 5;

(b) data on the medical surveillance of the worker shall include: –

(i) the medical classification of the worker in accordance with Regulation 46 (fit; fit, subject to certain conditions; unfit);

(ii) information on any restrictions on working with radiation;

(iii) the date of the last periodic health review; and

(iv) the period of validity of the result.

(c) the results of the outside worker's individual exposure monitoring in accordance with Part A, point 6, and at least for the last 5 calendar years including the current year.

2. The following data shall be recorded or have been recorded by the undertaking in the radiation passbook after the end of any work activity: –

(a) the period covered by the work activity;

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

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

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

C. Provisions concerning the radiation passbook

1. The Agency shall issue, on request, a radiation passbook for every outside worker.

2. The radiation passbook shall be non-transferable.

3. The Agency shall take the measures necessary to prevent a worker from being issued with more than one valid radiation passbook at the same time.

4. In addition to the information required in Part A and Part B, the radiation passbook shall include the name and address of the issuing body and the issuing date.

SCHEDULE 10

Indicative list of types of building materials considered with regard to their emitted gamma radiation as referred to in Regulation 67

1. Natural materials

(a) Alum-shale.

(b) Building materials or additives of natural igneous origin, such as: –

- granitoides (such as granites, syenite and orthogneiss);
- porphyries;
- tuff;
- pozzolana (pozzolanic ash);
- lava.

2. Materials incorporating residues from industries processing naturally-occurring radioactive material, such as: –

- fly ash;
- phosphogypsum;
- phosphorus slag;
- tin slag;
- copper slag;
- red mud (residue from aluminium production);
- residues from steel production.

SCHEDULE 11

Information to be provided in the records for high-activity sealed sources (HASS) as referred to in Regulation 72

STANDARD RECORD SHEET FOR HIGH-ACTIVITY SEALED SOURCES (HASS) *(optional in italics)*

1. HASS identification number

Manufacturer device number

Fields of use:

2. Identification of the licenced undertaking

Name:
Address:
Country:

Manufacturer ☐ Suplier ☐ User ☐

3. Location of HASS (Use or storage) if not the same as in 2.

Name:
Address:
Country:

Fixed use ☐ Storage ☐ Mobile use ☐

4. Recording

Date of start of recording:
Date of transfer of records to historic file:

5. Licence

Number:
Date of issue:
Date of expiry:

6. Operational controls of HASS

Date:
Date:
Date:

7. HASS characteristics

Year of manufacture:
Radionuclide:
Activity at the date of manufacturing:

Activity reference date:
Manufacturer/Supplier (*):
Name:
Address:
Country:

8. Receipt of HASS

Receipt from:

Name:
Address:
Country:

Manufacturer ☐ Supplier ☐ Another user ☐

Date of receipt:

Date:
Date:
Date:
Date:
Date:
Date:
Date:
Date:

9. Transfer of HASS

Date of transfer:

Transfer to:

Name:
Address:
Country:

Licence number:
Date of issue:
Date of expiry:

Manufacturer ☐ Supplier ☐ Other undertaking ☐

Facility for long term storage or disposal ☐

10. Further information

Loss ☐ Date of loss:
Theft ☐ Date of theft:
Findings: *Yes* ☐ *No* ☐
Date:
Place:

Other information:

Country:
Physical and chemical characteristics
Source type identification:
Capsule identification:
ISO classification:
ANSI classification:
LAEA source category:
Neutron source: *Yes* ☐ *No* ☐
Neutron source target:
Neutron flux:

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

SCHEDULE 12

Requirements for undertakings responsible for a high-activity sealed source as referred to in Regulation 74

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

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

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

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

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

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

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

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

SCHEDULE 13

Identification and marking of high-activity sealed sources as referred to in Regulation 74

1. The manufacturer or supplier ensures that: –

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

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

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

2. The manufacturer provides a photograph of each manufactured source design type and a photograph of the typical source container.

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

SCHEDULE 14

List of items to be considered in preparing the National Radon Control Strategy to address long-term risks from radon exposures as referred to in Regulation 64

(1) Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and radium-226 content of rock or soil).

(2) Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.

(3) Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a risk assessment, considering for instance occupancy hours.

(4) The basis for the establishment of reference levels for dwellings and workplaces. If applicable, the basis for the establishment of different reference levels for different uses of buildings (dwellings, buildings with public access, workplaces) as well as for existing and for new buildings.

(5) Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.

(6) Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under point 2.

(7) Strategies for facilitating post construction remedial action.

(8) Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.

(9) Schedules for reviews of the action plan.

(10) Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking.

(11) Guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.

(12) Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.

(13) Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non-smokers).

(14) Where appropriate, consideration of other related issues and corresponding programmes such as programmes on energy saving and indoor air quality.

SCHEDULE 15

Elements to be included in an emergency response plan

For emergency preparedness: –

1. Reference levels for public exposure in accordance with Regulation 21;

2. Reference levels for emergency occupational exposure in accordance with Regulation 62;

3. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;

4. Predefined generic criteria for particular protective measures;

5. Default triggers or operational criteria such as observables and indicators of on-scene conditions;

6. Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other Member States and with third countries which may be involved or are likely to be affected;

7. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

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

For emergency response: –

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

1. Promptly implementing protective measures, if possible, before any exposure occurs;

2. Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;

3. Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;

4. Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

SCHEDULE 16

Information to members of the public about health protection measures to be applied and steps to be taken in the event of a national emergency exposure situation as referred to in Regulation 55.

A. Prior information to the members of the public likely to be affected by an emergency

1. Basic facts about radioactivity and its effects on human beings and on the environment;

2. The various types of emergency covered and their consequences for the public and the environment;

3. Emergency measures envisaged to alert, protect and assist the public in the event of an emergency;

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

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

1. The members of the public actually affected in the event of an emergency shall rapidly and regularly receive: ─

(a) information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);

(b) advice on protection, which, depending on the type of emergency, may: ─

(i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements;

(ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public;

(c) announcements recommending cooperation with instructions or requests by the competent authority.

2. If the emergency is preceded by a pre-alarm phase, the members of the public likely to be affected shall already receive information and advice during that phase, such as: ─

(a) an invitation to the members of the public concerned to tune in to relevant communication channels;

(b) preparatory advice to establishments with particular collective responsibilities; and

(c) recommendations to occupational groups particularly affected.

3. This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment

GIVEN under my Official Seal of the Minister for Communications, Climate Action and Environment,
4 February 2019

RICHARD BRUTON
Minister for Communications, Climate Action and Environment.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

This Statutory Instrument transposes Council Directive 2013/59/EURATOM of 5 December 2013 (the Basic Safety Standards Directive), as affected by Corrigendum to Council Directive 2013/59/EURATOM, 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. The Basic Safety Standards Directive establishes basic safety standards for the protection of the health of individuals subject to occupational and public exposures against the dangers arising from ionising radiation.

These Regulations also transpose certain provisions of Council Directive 2011/70/EURATOM of 19 July 2011 (the Nuclear Waste Directive), establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste.

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