SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4431 of 25 January, 2018

LEGAL NOTICE NO. 24 OF 2018.

HEALTH PROTECTION (IONISING RADIATION) ACT 1995

INTERPRETATION AND GENERAL CLAUSES ACT

IONISING RADIATION REGULATIONS 2018

In exercise of the powers conferred upon it by section 2 of the Health Protection (Ionising Radiation) Act 1995, and section 23(g)(ii) of the Interpretation and General Clauses Act, and for the purposes of transposing into the law of Gibraltar Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, the Government has made the following Regulations-

Title.

1. These Regulations may be cited as the Ionising Radiation Regulations 2018.

Commencement.

2. These Regulations come into operation on 6 February 2018.

Amendment of the Ionising Radiation Regulations 2004.

3.(1) The Ionising Radiation Regulations 2004 is amended in accordance with the provisions of this regulation.

(2) Regulation 2 is amended as follow-

(a) the definition of "the 1995 Regulations" is deleted;

(b) before the definition of "accelerator" insert-

""absorbed dose" means D as in energy absorbed per unit mass, as-

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

where-

$d\bar{\varepsilon}$ is the mean energy imparted by ionising radiation to the matter in a volume element;

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

and in these Regulations, absorbed dose denotes the dose averaged over a tissue or an organ, with the unit for absorbed dose being the gray (Gy) where one gray is equal to one joule per kg;";

(c) after the definition of "accelerator" insert-

""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" means A as in the activity of an amount of a radionuclide in a particular energy state at a given time: where 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, expressed by-

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

where the unit of activity in the Becquerel.";

(d) in the definition of "appointed doctor" the words ", subject to regulation 52(5) (which is a transitional provision)," are deleted;

(e) after the definition of "appointed doctor" insert-

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

(f) for the definition of "approved dosimetry service" substitute-

""approved dosimetry service" means a body or an individual, approved in accordance with regulation 37, as being 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;

"authorisation" means an authorisation granted under regulation 6A;

"Bq" means Becquerel, which is the special name of the unit of activity, and one Becquerel is equivalent to one nuclear transition per second;

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

(g) the definition of "classified person" is amended as follows-

(i) for "another member" substitute "a Member",

(ii) for "21" substitute "40";

(h) after the definition of "classified person" insert-

""clearance levels" means values established by the competent authority or in Gibraltar law, 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 the Directive;";

(i) after the definition of "comforter and carer" insert-

""committed effective dose" means (E(τ)) as the sum of the committed organ or tissue equivalent doses HT(τ) resulting from an intake, each multiplied by the appropriate tissue weighting factor wT: and it is expressed by-

$$E(\tau) = \sum_{T} w_T H_T(\tau)$$

, and

in specifying E(τ), is given in the number of years over which the integration is made, and for the purposes of complying with dose limits under these Regulations is-

(a) a period of 50 years following intake for adults; and

(b) up to the age of 70 for infants and children,

where the unit for committed effective dose is the Sievert;

"committed equivalent dose" means (HT(τ)) as 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, and is expressed 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; and

τ is the time over which the integration is performed,

and in specifying HT(τ), is given in number of years over which the integration is made, and for the purposes of

complying with dose limits under these Regulations is-

(a) τ is a period of 50 years for adults; and

(b) up to the age of 70 for infants and children,

where the unit for committed effective dose is the Sievert;";

(j) after the definition of "competent authority" insert-

""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;";

(k) for the definition of "contamination" substitute-

""contamination" means the unintended and undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body, and "contaminated" is to be construed accordingly;";

(l) the definition of "controlled area" is amended as follows-

(i) for "another member" substitute "a Member",

(ii) for "19" substitute "37";

(m) for the definition of "the Directive" substitute-

""the 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, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom;

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

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

(n) for the definition of "dose constraint" substitute-

""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;";

(o) after the definition of "dose record" insert-

""effective dose" means the sum of the weighted equivalent doses in all the tissues and organs of the body from internal and external exposure, and is defined by the expression-

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

,

and further defined in Schedule 11;

"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 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;

"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" means the absorbed dose, in tissue or organ T weighted for the type and quality of radiation R, and is defined by the expression-

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

and further defined in Schedule 11;

"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;

"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);";

(p) after the definition of "external radiation" insert-

""extremities" means a person's hands, forearms, feet and ankles;

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

(q) in the definition of "health record" the words "subject to regulation 52(7) (which is a transitional provision)," are deleted;

(r) after the definition of "health record" insert-

""high-activity sealed source" means a sealed source for which the activity of the radionuclide is equal to or exceeds the relevant activity value set out in Schedule 9;

"industrial irradiation" means the use of ionising radiation to sterilise, process or alter the structure of products or materials;

"industrial radiography" means the use of ionising radiation for non-destructive testing purposes where an image of the item under test is formed, but excluding any such testing which is carried out in a cabinet which a person cannot enter;

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

(s) after the definition of "internal radiation" insert-

""International Headquarters and Defence Organisations Act 1964" means the International Headquarters and Defence Organisations Act 1964 passed by the Parliament at Westminster;";

(t) for the definition of "medical exposure" substitute-

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

"medical physics expert" means a person who holds a science degree or its equivalent and who is experienced to act or give evidence in the application of physics to the diagnostic and therapeutic uses of ionising radiation;

"medical radiological" means pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional

radiology or other medical uses of ionising radiation for planning, guiding and verification purposes;";

(u) for the definition of "member State" substitute-

""Member State" means a Member State of the European Union;

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

(v) after the definition of "the Minister" insert-

""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;

"occupational exposure" 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 competent authority;

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

(w) after the definition of "overexposure" insert-

""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 planned exposure situations may include both normal exposures and potential exposures;

"potential exposure" means exposure that is not expected with certainty but may result from an event or

sequence of events of a probabilistic nature, including equipment failures and operating errors;";

(x) for the definition of "practice" substitute-

""practice" means work involving-

(a) the production, processing, handling, use, holding, storage, transport or disposal of radioactive substances; or

(b) the operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5kV,

which can increase the exposure of individuals to ionising radiation;

"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: and quality control is a part of quality assurance;";

(y) in the definition of "radiation employer" after the words "6," insert "6A,";

(z) after the definition of "radiation employer" insert-

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

(aa) the definition of "radiation passbook" is amended as follows-

(i) in paragraph (a)(ii) for "52" substitute "53",

(ii) in paragraph (b) for "another member" substitute "a Member",

(iii) in paragraph (b) for "other member" substitute "a Member";

(bb) after the definition of "radiation protection adviser" insert-

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

"radioactive material" means material incorporating radioactive substances;

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

(cc) after the definition of "radioactive substance" insert-

""radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered, and which is regulated as radioactive waste by a competent authority;

"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 a limit that may be exceeded;

"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;";

(dd) for the definition of "sealed source" substitute-

""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;";

(ee) after the definition of "short-lived daughters or radon 222" insert-

""sievert" or "Sv" means the special name of the unit of equivalent or effective dose, and one sievert is equivalent to one joule per kilogram;

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

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

"standard values and relationships" means values and relationships recommended in chapters 4 and 5 of ICRP Publication 116 for the estimation of doses

from external exposure and chapter 1 of ICRP Publication 119 for the estimation of doses from internal exposure, including updates approved by Member States;";

(ff) after the definition of "transport" insert-

""Visiting Forces Act 1952" means the Visiting Forces Act 1952 passed by the Parliament at Westminster;";

(gg) the definition of "woman of reproductive capacity" is deleted.

(3) Regulation 3 is amended as follows-

(a) for subregulation (1)(b) substitute-

"(b) any work, other than a practice, carried out in an atmosphere containing radon 222 gas at an annual average activity concentration in air exceeding 300 Bq m-3; and";

(b) in subregulation (2) for "24" substitute "25";

(c) in subregulation (3) after "27" insert ", 33(2)(a)";

(d) subregulation (5) is amended as follows-

(i) for "another member" substitute "a Member",

(ii) for "1999" substitute "2017",

(iii) for paragraph (c) substitute-

"(c) where the employer is established in a Member State, the legislation in that Member State which implements Chapter VI of the Directive, where such legislation exists.";

(e) after regulation 3 insert-

"Setting of reference levels.

3A.(1) When setting a reference level for the purposes of these Regulations, consideration shall be given to-

(a) radiological protection requirements and societal criterial; and

(b) the range of reference levels set out in Annex I to the Directive.

(2) Where a reference level has been set for an exposure situation, optimisation of radiation protection for individuals subject to the exposure shall be prioritised for exposures above the reference level, and optimisation shall be implemented below the reference level.".

(4) After Part I insert-

"**PART IA**

JUSTIFICATION AND REGULATORY CONTROL OF PRACTICES

Justification of types of practice.

4A.(1) No person shall carry out any practice resulting in exposure to ionising radiation which falls within a new class or type of practice unless the Minister has determined in writing that that new class or type of practice is justified by its economic, social or other benefits in relation to the health detriment it may cause.

(2) Whenever there is-

(a) new and important evidence as to the efficacy or consequences of an existing class or type of practice; or

(b) new and important information about other techniques and technologies,

the Minister may review that class or type of practice in order to determine whether it is justified by its economic, social or other benefits in relation to the health detriment it may cause.

(3) A class or type of practice involving occupational and public exposures is to be justified taking into account both categories of exposure, and the identification of classes or types of practices involving naturally-occurring radioactive material shall be carried out by appropriate means taking into account the industrial sectors listed in Schedule 12.

(4) Where, pursuant to subregulation (2), the Minister determines that an existing class or type of practice is not justified, he shall prohibit in writing the carrying on of that class or type of practice and, subject to subregulation (5), thereafter no person shall carry on any practice which falls within that class or type of practice.

(5) The Minister may make any prohibition pursuant to subregulation (4) subject to such incidental or transitional provisions as he considers appropriate.

(6) The Minister shall take such steps as he considers appropriate to make public-

(a) any determination made pursuant to subregulation (1) or (2); or

(b) any prohibition made pursuant to subregulation (4).

(7) Prior to determining whether a new or existing class or type of practice is justified pursuant to subregulation (1) or (2), the Minister shall consult-

(a) the competent authority;

(b) where the class or type of practice involves work with any radioactive substance, the Environmental Agency; and

(c) any other person or body which the Minister considers appropriate.

(8) Where, having consulted others pursuant to subregulation (7), the Minister is of the opinion that the new or existing class or type of practice may not be justified, he shall-

(a) afford the person seeking the determination an opportunity to make representations to him before making any determination pursuant to subregulation (1) or (2); and

(b) take such steps as it considers appropriate to bring the proposed prohibition to the attention of any person who is carrying on a practice of such class or type and who may be directly affected by that prohibition.

(9) Notwithstanding the provisions of subregulations (1) and (4), the deliberate addition of any radioactive substance in the production of any of the following shall be prohibited-

(a) any toy;

(b) any personal ornament; and

(c) any cosmetic.

(10) In this regulation, "new class or type of practice" means a class or type of practice for which-

(a) no practice in that class or type was carried out in Gibraltar before 6 February 2018; or

(b) a practice in that class or type was carried out in Gibraltar before 6 February 2018 but in breach of a requirement not to carry out such practice,

and in either case the class or type of practice has not been found to be justified.

(11) Proceedings for an offence under this regulation shall not be instituted without the consent of the Attorney General.

(12) Nothing in subregulation (1) or (4) shall prevent, in relation to a medical exposure, the administering of a specific individual exposure to ionising radiation permitted by the Ionising Radiation (Administration of Radioactive Medicinal Products and Medical Exposures) Regulations 2002.

(13) This Regulation does not apply to activities on board, or related to, visiting nuclear powered warships.

(14) Any justification decision made by the Minister under this regulation may be made subject to such conditions as the Minister may consider appropriate.

(15) Where the Secretary of State determines that, for overriding reasons of national security, it is necessary for any function under this regulation to be exercised by the Secretary of State, any reference to the Minister in this Regulation shall be construed as a reference to the Secretary of State.

Practices involving consumer products.

4B.(1) Any person 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, prior to commencing the manufacture or import, provide the Minister with all the relevant information necessary to make a determination for justification, including-

(a) the intended use of the product;

(b) the technical characterisations of the product;

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

(d) dose rates at relevant distances for the use of the product, including dose rates at a distance of 0.1m from any accessible surface; and

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

(2) In deciding whether the intended use of the consumer product is justified the Minister shall take into account whether-

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

(b) the design is adequate in order to minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures, or whether there

should be conditions imposed on the technical and physical characteristics of the product;

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

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

(3) Without prejudice to subregulation (1) the Minister shall ensure that the competent authority and competent authorities of Member States are-

(a) informed of any contact made by a person intending to manufacture or import a consumer product under subregulation (1); and

(b) informed, upon request, of the Minister's decision and basis for that decision.

(4) No person shall knowingly or recklessly-

(a) add any radioactive substance in the production of foodstuffs, animal feeding stuffs, and cosmetics;

(b) add any radioactive substance in the manufacture of toys and personal ornaments;

(c) manufacture, sell, or make available to the public any toys or personal ornaments, the intended use of which involves the activation of materials, where that activation results-

(i) at the time of sale of the product, or

(ii) at the time of their manufacture,

in an increase in activity which cannot be disregarded from a radiation protection point of view; or

(d) import or export any of the products in paragraphs (a) to (c).

(5) A class or type of practice involving activation of material resulting in an increase in activity in a consumer product, which at the time of sale of that consumer product, cannot be disregarded from a radiation protection point of view, is "new" for the purposes of this Part if that class or type of practice has not been found to be justified.

(6) The sale or the making available to the public of consumer products, if their intended use is not justified or their use would not fulfil the criteria for exemption from notification under Schedule 1, is prohibited.

Practices involving non-medical imaging exposure.

4C.(1) The Minister shall ensure that practices involving non-medical imaging exposure are identified, in particular taking into account the following practices-

(a) practices using medical radiological equipment for-

(i) radiological health assessment for employment purposes,

(ii) radiological health assessment for immigration purposes,

(iii) radiological health assessment for insurance purposes,

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

(v) radiological age assessment,

(vi) use of ionising radiation for the identification of concealed objects within the human body.

(b) practices not using medical radiological equipment for-

(i) use of ionising radiation for detection of concealed objects on or attached to the human body,

(ii) use of ionising radiation for detection of concealed humans as part of cargo screening,

(iii) practices involving the use of ionising radiation for legal or security purposes.

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

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

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

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

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

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

(3) The Minister may exempt justified practices involving non-medical imaging exposure using medical radiological equipment from the requirement for dose constraints, and from the dose limits set out in regulation 12.

(4) Where the Minister has justified a particular practice involving non-medical imaging exposure, the competent authority shall ensure that-

(a) the practice is subject to authorisation;

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

(c) for procedures using medical radiological equipment-

(i) relevant requirements identified for medical exposure as set out in the Ionising Radiation (Administration of Radioactive Medicinal Products and Medical Exposures) Regulations 2002 are applied, including those for equipment, optimisation, responsibilities, training and special protection during pregnancy and the appropriate involvement of the medical physics expert,

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

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

(d) for procedures not using medical radiological equipment, dose constraints are significantly below the dose limit for members of the public;

(e) information is provided to and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities may proceed without consent of the individual according to Gibraltar law.".

(5) Regulation 5 is deleted.

(6) For regulation 6 substitute-

"**Registration of certain practices.**

6.(1) Subject to subregulation (3), an employer shall not carry out any of the practices listed in subregulation (2) "registrable practices" unless-

(a) he has registered the practice in accordance with the registration procedure approved by the competent authority from time to time;

(b) he provides to the competent authority any such additional particulars in relation to the practice as the competent authority may reasonably require in connection with the registration.

(2) The following are registrable practices-

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

(b) any other work involving ionising radiation, which is not a specified practice under regulation 6A.

(3) Registration by the competent authority under subregulation (1)(a) may be granted in accordance with such conditions, with or without limit of time, as the competent authority may impose in connection with the registration.

(4) Registration may be refused or revoked at any time by the competent authority if it reasonably believes that-

(a) harm is being caused to employees or the public; or

(b) conditions imposed on the registration are not being upheld.

(5) Where an employer subsequently ceases to carry out, or makes a material change, to a practice that he has registered under subregulation (1)(a), which would affect the particulars relating to the registration as to no longer make it accurate, the employer shall

notify the competent authority, as soon as practically possible, of that cessation or material change.

(6) An employer who is aggrieved by-

(a) a refusal to register;

(b) any conditions imposed on registration;

(c) any limit of time imposed on registration; or

(d) the revocation of registration,

may appeal, in writing, to the Minister with 28 days of the decision to refuse, revoke, or impose a limit of time or conditions on the registration.

(7) The Minister may, in such cases as he considers it appropriate to do so, having regard to the nature of the questions which appear to him to arise, direct that an appeal under this regulation shall be determined on his behalf by a person appointed by him for that purpose.

(8) Before the determination of an appeal the Minister shall ask the appellant and the competent authority whether they wish to appear and be heard on the appeal and-

(a) the appeal may be determined without a hearing of the parties if both of them express a wish not to be heard as aforesaid;

(b) the Minister shall, if either of the parties expresses a wish to appear and be heard, afford both to both of them an opportunity of so doing.

(9) The person who determines an appeal under this regulation (whether it be the Minister himself or another person appointed by him to do so on his behalf) may give such directions as he considers appropriate to give effect to his determination.

(10) The Minister may pay to any person appointed to hear or determine an appeal under this regulation on his behalf such remuneration and allowances as the Minister may determine.".

(7) After regulation 6 insert-

"**Authorisation of specified practices.**

6A.(1) Except in accordance with a prior written authorisation granted by the competent authority, an employer shall not carry out any of the following practices "specified practice"-

(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, except aboard a visiting nuclear powered warship, and decommissioning of any nuclear facility and the exploitation and closure of uranium mines;

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

(d) any practice involving a high-activity sealed source, other than one within paragraphs (h) or (i);

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

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

(g) the operation of radiation generators or accelerators, except electron microscopes, or radioactive sources for purposes not covered by regulation 6(2)(a);

(h) industrial irradiation;

(i) industrial radiography;

(j) the disposal, recycling or reuse of radioactive substances or materials arising from any practice referred to in paragraphs (a) to (g).

(2) An employer wanting to carry out a specified practice under subregulation (1) shall apply in writing for authorisation, in accordance with the authorisation procedure approved by the competent authority from time to time.

(3) An employer applying for authorisation under subregulation (2) shall provide-

(a) such of the information set out in Schedule 1A as the competent authority may specify from time to time as necessary to determine the application for authorisation;

(b) upon notice in writing, such other information relating to the practice as the competent authority may reasonably require in connection with the application for authorisation.

(4) Authorisation by the competent authority under this regulation may be granted in accordance with such conditions, with or without limit of time, as the competent authority may impose in connection with the authorisation.

(5) Authorisation may be refused or revoked at any time by the competent authority if it reasonably believes that-

(a) harm is being caused to employees or the public; or

(b) conditions imposed on the authorisation are not being upheld.

(6) Where an employer subsequently ceases to carry out, or makes a material change, to a practice that he has received authorisation for, which would affect the particulars relating to the authorisation as to no longer make it accurate, the employer shall notify the competent authority, as soon as practically possible, of that cessation or material change.

(7) An employer who is aggrieved by-

(a) a refusal for authorisation;

(b) any conditions imposed on an authorisation;

(c) any limit of time imposed on an authorisation; or

(d) the revocation of an authorisation,

may appeal, in writing, to the Minister with 28 days of the decision to refuse, revoke, or impose a limit of time or conditions on the authorisation.

(8) The Minister may, in such cases as he considers it appropriate to do so, having regard to the nature of the questions which appear to him to arise, direct that an appeal under this regulation shall be determined on his behalf by a person appointed by him for that purpose.

(9) Before the determination of an appeal the Minister shall ask the appellant and the competent authority whether they wish to appear and be heard on the appeal and-

(a) the appeal may be determined without a hearing of the parties if both of them express a wish not to be heard as aforesaid;

(b) the Minister shall, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing.

(10) The person who determines an appeal under this regulation, whether it be the Minister himself or another person appointed by him to do so on his behalf, may give such directions as he considers appropriate to give effect to his determination.

(11) The Minister may pay to any person appointed to hear or determine an appeal under this regulation on his behalf such remuneration and allowances as the Minister may determine.

(12) Subject to subregulation (13), materials for the disposal, recycling or reuse may be released from the need for authorisation by the competent authority provided that the activity concentrations-

(a) for solid material do not exceed the clearance levels set out in Table A of Annex VII to the Directive; or

(b) comply with specific clearance levels, established by the competent authority, and associated requirements for specific materials or for materials originating from specific types of practices.

(13) If clearance levels are set under subregulation (12)(b), consideration shall be had of the general exemption and clearance criteria set out in Schedule 1 and any available technical guidance.

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

(15) Subject to subregulation (16), the deliberate dilution of radioactive materials for the purpose of releasing them from regulatory control in accordance with subregulation (12) shall not be allowed by the competent authority.

(16) The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to the prohibition under subregulation (15).

(17) The competent authority may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of reuse or recycling.".

(8) Regulation 7 is amended as follows-

(a) for subregulation (1) substitute-

"7.(1) This regulation shall apply to work with ionising radiation other than-

(a) work arising from the carrying out of a registrable practice under regulation 6 or a specified practice requiring authorisation under regulation 6A;

(b) work specified in Schedule 1.";

(b) after subregulation (1) insert-

" (1A) Notwithstanding any exemption from notification that may be provided under these Regulations, where a practice may lead to the presence of naturally-occurring radionuclides in water liable to-

(a) affect the quality of drinking water supplies; or

(b) affect any other exposure pathway,

so as to be a concern from a radiation protection point of view, the competent authority may require that practice to be subject to notification.";

(c) in subregulation (2) for "52" substitute "53";

(d) in subregulation (5) after "employer subsequently" insert "ceases to work, or";

(e) in subregulation (8) for "1995" substitute "2002".

(9) Regulation 9 is amended as follows-

(a) for subregulation (2)(c) substitute-

"(c) by the provision of adequate and suitable personal protective equipment, including respiratory protective equipment, unless the use of personal protective equipment of a particular kind is not appropriate having regard to the nature of the work or the circumstances of the particular case.";

(b) after subregulation (4) insert-

"(4A) A radiation employer shall establish the dose constraints referred to in subregulation (4) in terms of the effective or equivalent dose received by an individual over an appropriate period of time.";

(c) in subregulation (5)(b) after "significant risk" insert " of intake of radionuclides or".

(10) For regulation 12(2) substitute-

"(2) Where an employer is able to demonstrate to the competent authority that, in respect of an employee, the dose limit specified in paragraph 1 of Schedule 4 is impracticable having regard to the nature of the work undertaken by that employee, the competent authority may in respect of that employee authorise the employer to apply the dose limits set out in paragraphs 9 or 10 of Schedule 4 and in such case the provisions of Part II of that Schedule will have effect.

(3) The steps taken by a relevant employer to comply with subregulation (1) in respect of members of the public shall include an estimation of doses to members of the public from the relevant practice or practices carried out by the relevant employer in accordance with requirements regarding the estimation of doses as approved by the competent authority from time to time.

(4) When considering the estimation of doses to the members of the public the competent authority, where appropriate, shall-

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

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

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

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

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

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

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

(5) In this regulation "relevant practice" means a practice to which regulations 6 or 6A applies.".

(11) Regulation 13 is amended as follows-

(a) in paragraph (a)(ii) the last "and" is deleted;

(b) in paragraph (b) for "." Substitute "; and";

(c) after paragraph (b) insert-

"(c) in circumstances where it is necessary for some or all of the arrangements in the plan to be carried out-

(i) the cause of those circumstances is analysed to determine, so far as is reasonably practicable, the measures, if any, required to prevent a recurrence of such circumstances,

(ii) a record of such analysis is made and kept for at least 2 years from the date on which it was made, and

(iii) any exposure which occurs due to the above circumstances is noted on any relevant dose record.".

(12) After regulation 14(4) insert-

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

(13) For regulation 15 substitute-

"**Information, instruction and training.**

15.(1) Every radiation employer shall ensure that-

(a) those of his employees who are engaged in work with ionising radiation are given suitable and sufficient information, instruction and training in the field of radiation protection (having regard to the specific work to be carried out) for the purpose of ensuring that they know-

(i) the risks to health created by exposure to ionising radiation as a result of their work,

(ii) the general and specific radiation protection procedures and precautions which should be taken in connection with the work with ionising radiation to which they may be assigned,

(iii) the importance of complying with the administrative, medical and technical requirements of these Regulations, and

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

(b) any of his female employees who are engaged in work with ionising radiation are informed of the possible risk arising from ionising radiation to the foetus and to a nursing infant and of the importance of their informing their employer in writing as soon as reasonably practicable-

(i) after becoming aware of their pregnancy, or

(ii) if they intend to breastfeed an infant;

(c) adequate information is given to any other person who is directly concerned with the work with ionising radiation carried out by the radiation employer, for the purpose of ensuring, so far as is reasonably practicable, that person's health and safety;

(d) any employees engaged in work in a controlled area are given specific training in connection with the characteristics of the workplace and the activities within it; and

(e) the giving of training and information under this regulation is repeated at appropriate intervals and documented by the employer.

(2) The competent authority shall ensure that the management of an installation where orphan sources are most likely to be found or processed are informed of the possibility that they may be confronted with a source.

(3) The management of an installation under subregulation (2) shall ensure that employees in the installation, who may be confronted with a source, are-

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

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

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

(4) In relation to high-activity sealed sources, the appropriate training and adequate information under subregulation (1) shall include-

(a) specific requirements for the safe management of such a source;

(b) particular emphasis on the necessary safety requirements in relation to such a source; and

(c) specific information on possible consequences of the loss of adequate control of such a source,

and the training and information shall be repeated at regular intervals and documented, with a view to preparing the employees for such matters.

(5) A radiation employer shall ensure that emergency workers who are identified in an emergency response plan or off-site emergency response plan are-

(a) given adequate and regularly updated information on the health risks their intervention might involve;

(b) given adequate information on the precautionary measures to be taken in such an event; and

(c) provided with appropriate radiation protection training and information,

and this information should take into account the range of potential emergencies and the type of intervention.

(6) As soon as an emergency occurs, the information referred to in subregulation (5) shall be supplemented appropriately, having regard to the specific circumstances.

(7) Where appropriate, the competent authority shall ensure that emergency workers are provided with adequate training in regards

to any off-site emergency response plan under the Radiation (Emergency Preparedness and Public Information) Regulations 2004.".

(14) After regulation 16 insert-

"PART IIIA

EXISTING EXPOSURE SITUATIONS

Operation protection of members of the public.

16A.(1) The competent authority shall ensure that the operational protection of members of the public in normal circumstances from practices subject to authorisation shall include, for relevant facilities, the following-

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

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

(c) examination and approval of plans for the discharge of radioactive effluents; and

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

(2) The competent authority shall, where appropriate, establish authorised limits as part of the discharge authorisation and conditions for discharging radioactive effluents which shall-

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

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

(3) An employer with responsibility for practices where a discharge authorisation is granted shall-

(a) monitor appropriately; or

(b) where appropriate, evaluate,

The radioactive airborne or liquid discharges into the environment in normal operation, and report the results to the competent authority.

Programmes on existing exposure situations.

16B.(1) The competent authority shall ensure that measures are taken, upon indication or evidence of exposures that cannot be disregarded from a radiation protection point of view, to-

(a) identify and evaluate existing exposure situations taking into account the types of existing exposure situations listed in Schedule 13; and

(b) determine the corresponding occupational and public exposures.

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

Establishment and implementation of strategies.

16C.(1) The competent authority shall arrange, where appropriate, for the establishment of strategies to ensure the appropriate management of existing exposure situations commensurate with the risks and with the effectiveness of protective measures.

(2) Each strategy established in accordance with subregulation (1) shall contain-

(a) the objectives pursued; and

(b) appropriate reference levels, taking into account the reference levels laid down in Schedule 15.

(3) The competent authority shall assign responsibilities for the implementation of strategies for the management of existing exposure situations, and ensure appropriate coordination between relevant parties involved in the implementation of remedial and protective measures.

(4) The distribution of doses that has resulted from the implementation strategies shall be assessed, and further efforts shall be considered if need be, with the view to optimising protection and reducing any exposures that are still above the reference levels.

(5) The competent authority, where appropriate, shall-

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

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

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

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

Radiation action plan.

16D.(1) If there are any long-term risks of radon exposure in any buildings or workplaces as a result of a source of radon ingress, the competent authority shall, by whatever means it deems appropriate, establish a plan for addressing these risks.

(2) In developing the plan under subregulation (1) the competent authority shall take into account the issues set out in Schedule 16, and identify any areas where the radon concentration, taken as an annual average, exceeds the reference level established under regulation 3(1)(b).

Environmental monitoring and contaminated areas.

16E.(1) The competent authority shall, where appropriate, undertake appropriate environmental monitoring.

(2) If an area appears to be contaminated, the competent authority shall, where appropriate, investigate and manage the situation by considering-

(a) objectives, including long-term goals pursued by the strategy and corresponding reference levels;

(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.

(3) Before the resumption of habitation, economic or social activities on an area which is contaminated as a result of the after-effects of an emergency, past practice or past work activity and which cannot be disregarded from a radiation protection point of view, the competent authority shall ensure that arrangements are in place, as appropriate, for the on-going control of exposure to ionising radiation with the aim of establishing living conditions that can be considered as normal, including-

(a) setting of appropriate reference levels;

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

(c) remediation measures;

(d) the delineation of areas.

Building materials.

16F.(1) The reference level applying to indoor external exposure to gamma radiation emitted by building materials, in addition to outdoor external exposure, shall be 1 mSv per year.

(2) If an employer is aware that a building material is of concern from a radiation protection point of view, taking into account the indicative list in Schedule 17, it shall ensure that before such building material is used-

(a) the activity concentrations of the radionuclides specified in Schedule 18 are determined; and

(b) if requested, the competent authority is provided with information on the results of measurements and the corresponding activity concentration index, as well as other relevant factors, as defined in Schedule 18.".

(15) For regulation 17(1)(b) substitute-

"(b) any person working in that area is likely to receive an effective dose of ionising radiation-

(i) greater than 6mSv per year, or

(ii) an equivalent dose greater than 15mSv per year for the lens of the eye, or

(iii) an equivalent dose greater than 150mSv per year for the skin or the extremities,

the employer shall designate that area as a controlled area.".

(16) For regulation 18(b) substitute-

"(b) any person entering that area is likely to receive an effective dose of ionising radiation-

(i) greater than 1mSv a year, or

(ii) an equivalent dose of 5mSv per year for the lens of the eye, or

(iii) an equivalent dose greater than 50 mSv per year for the skin and the extremities,

the employer shall designate that area as a supervised area.".

(17) Regulation 19 is amended as follows-

(a) after subregulation (1) insert-

"(1A) Local rules shall identify the main working instrcutions intended to restrict any exposure in that controlled or suerpvised area.";

(b) after regulation (4) insert-

"(4A) The responsibilities of the radiation protection supervisor may be carried out by-

(a) a radiation protection unit established by the radiation employer; or

(b) a radiation protection adviser.".

(18) Regulation 20 is amended as follows-

(a) in subregulation (6)(b) after "in the ingestion" insert ", inhalation or absorption";

(b) for subregulation (6)(c) substitute-

"(c) the means for monitoring contamination-

(i) within a controlled area and, where appropriate, in the adjacent area, and

(ii) on any person, article or goods leaving a controlled area.".

(19) Regulation 21 is amended as follows-

(a) after subregulation (1) insert-

"(1A) Adequate monitoring referred to in subregulation (1) shall include-

(a) in relation to areas designated on the basis of external radiation, measurement of dose rates, averaged over a suitable period if necessary; and

(b) in relation to areas designated on the basis of internal radiation, measurements of air activity and surface contamination where appropriate taking into account the physical and chemical states of the radioactive contamination.";

(b) after subregulation (3) insert-

"(4) Suitable records of the results of the monitoring referred to in subregulation (3)(a) shall include-

(a) in relation to areas designated on the basis of external radiation, an indication of the nature and quality of the radiation in question;

(b) in relation to areas designated on the basis of internal radiation, an indication, where appropriate, of the nature and physical and chemical states of the radioactive contamination.".

(20) After regulation 21 insert-

"**Arrangements in workplaces.**

21A.(1) Workplaces where-

(a) the radon concentration continues to exceed the reference level at regulation 3(1)(b); and

(b) the exposure of workers is liable to exceed an effective dose of 6 mSv per year,

shall be managed as a planned exposure situation, with the competent authority determining which requirements under this Part are appropriate.

(2) Pursuant to subregulation (1), where the effective dose to workers is less than or equal to 6 mSv per

year the competent authority shall require that the exposure be kept under review.

(3) If the employer operates a commercial aircraft registered in Gibraltar, where the effective dose to the crew from cosmic radiation is liable to exceed 6 mSv per year, this Part shall apply, allowing for the specific features of this exposure situation.

(4) Pursuant to subregulation (3) where the effective dose to the crew is liable to be above 1 mSv per year, the competent authority shall require that the employer take appropriate measures, in particular-

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

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

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

(d) to apply regulation 9(6) to pregnant air crew.".

(21) Regulation 22 is amended as follows-

(a) for subregulation (1) substitute-

"22.(1) Subject to subregulation (2), the employer shall designate as a classified person any of his employees who is likely to receive an effective dose of ionising radiation-

(a) greater than 6mSv per year; or

(b) an equivalent dose greater than 15mSv per year for the lens of the eye; or

(c) an equivalent dose greater than 150 mSv per year for the skin or the extremities,

and shall immediately inform those employees that they have been so designated.";

(b) in subregulation (3)(b) for "his receiving an effective dose of ionising radiation in excess of 1mSv" substitute "significant exposure to ionising radiation".

(22) Regulation 23 is amended as follows-

(a) in subregulation (3) for "50" substitute "30";

(b) in subregulation (4)(h) for "another member" substitute "a Member".

(23) Regulation 25 is amended as follows-

(a) in subregulation (1) for "exceeding 6 mSv or an equivalent dose greater than three-tenths of any relevant dose limit," substitute "greater than 6mSv, or an equivalent dose greater than 15mSv for the lens of the eye, or greater than 150mSv for the skin or the extremities,";

(b) subregulation (2) is amended as follows-

(i) in paragraph (a) "and" is deleted,

(ii) in paragraph (b) for "50" substitute "30",

(iii) in paragraph (b) for "." substitute "; and",

(iv) after paragraph (b) insert-

"(c) notify the competent authority of the result of the dose assessment as soon as possible.".

(24) Regulation 26 is amended as follows-

(a) in subregulation (1)(c) for "(6)" substitute "(7)";

(b) in subregulation (3)(b) for "50" substitute "30";

(c) in subregulation (6) for "the 12 month" substitute "that";

(d) after subregulation (6) insert-

"(6A) In order to safeguard the health of the employee concerned, the appointed doctor may decide whether the employee requires continuing medical surveillance after cessation of the work concerned.".

(25) In regulation 27(4)(b)(ii) for "50" substitute "30".

(26) Regulation 32 is amended as follows-

(a) in subregulation (1) for "column 4" substitute "column 5 of Part 1";

(b) after subregulation (1) insert-

" (1A) Subregulation (1) does not apply where such release has been justified or exempted by the Minister.";

(c) in subregulation (2) for "column 5" substitute "column 6 of Part 1";

(d) in subregulation (4)(b) for "50" substitute "30".

(27) For subregulation 33 substitute-

"**Duties of manufactures etc. of articles for use in work with ionising radiation.**

33.(1) Where a person erects or installs an article for use in work with ionising radiation, he shall-

(a) undertake, where appropriate, a critical examination of the way in which the article was erected or installed, for the purpose of ensuring in particular that-

(i) the safety features and warning devices operate correctly, and

(ii) there is sufficient protection for persons from exposure to ionising radiation;

(b) consult with the radiation protection adviser, appointed by himself or by the radiation employer, regarding the nature and extent of any critical examination and the results thereof; and

(c) provide the radiation employer with adequate information about proper use, testing and maintenance of the article.

(2) It shall be the duty of any person who designs, manufactures, imports or supplies any article for use at work to-

(a) ensure, as far as reasonably practicable, that the article is so designed and constructed so that it restricts, as far as reasonably practicable, the extent to which employees and other persons are or are likely to be exposed to ionising radiation;

(b) carry out or arrange for the carrying out of such testing and examination as may be necessary for the performance of the duty imposed on him by the preceding paragraph;

(c) take such steps as are necessary to secure that persons supplied by that person with the article are provided with adequate information about the use for which the article is designed or has been tested and about any conditions necessary to ensure that it will be safe and without risks to health at all such times as are mentioned in paragraph (a) and when it is being dismantled or disposed of; and

(d) take such steps as are necessary to secure, so far as is reasonably practicable, that persons so supplied are provided with all such revisions of information provided to them by virtue of the preceding paragraph as are necessary by reason of its becoming known that anything gives rise to a serious risk to health or safety.".

(28) Regulation 34 is amended as follows-

(a) in subregulation (3) for "the date of the coming into force of these Regulations" substitute "6 February 2018";

(b) in subregulation (5) for "that" substitute "than";

(c) in subregulation (6)(b)(ii) for "50" substitute "30".

(29) After regulation 37(3) insert-

"(4) Subject to subregulaiton (5), for the estimation of effective and equivalent doses, the appropriate standard values and relationships shall be used.

(5) For external radiation, the operational quantities defined in section 2.3 of ICRP Publication 116 shall be used.".

(30) In regulation 38(2)(d) after "22(1)," insert "23(1),".

(31) After regulation 39(6) insert-

"(7) Nothing in this regulation shall confer any power of entry to a nuclear powered warship, or access to information relating to nuclear-powered warships which in the opinion of the Secretary of State would raise issues of national security.".

(32) Regulation 46 is amended as follows-

(a) for subregulation (1) insert-

"46.(1) In any proceedings against any person for an offence under regulation 6(1)(a), 6A(1) or 7(2), it shall be a defence for that person to prove that-

(a) he neither knew nor had reasonable cause to believe that his actions were in contravention of that subregulation; and

(b) in a case where he discovered that he had carried out or was carrying out work subject to notification under that provision, he had forthwith-

(i) notified the competent authority of his discovery, and

(ii) provided the authority with the particulars required by that provision.";

(b) for subregulation (2) substitute-

"(2) The defence in subregulation (1)-

(a) in connection with an offence under regulation 6(1)(a), does not apply in relation to the operation of a radiation generator; and

(b) in connection with an offence under regulation 6A(1), only applies in relation to a practice referred to in regulation 6A(1)(d).";

(c) in subregulation (6) after "as a controlled area" insert "or supervised area".

(33) Regulation 51 is amended as follows-

(a) for every reference to "Secretary of State for Defence" substitute "Secretary of State";

(b) in subregulation (3) for "Regulation 7" substitute "Regulations 6, 6A and 7";

(c) for subregulation (4) substitute-

"(4) With respect to any work with ionising radiation undertaken for, or on behalf, the Secretary of State-

(a) the requirements to notify particulars under regulations 6(1), 6A(3), and 7(2) and (3), shall only apply in relation to the particulars that may be so specified from the list set out in subregulation (4A); and

(b) any requirement to provide the particulars described in subregulations (4A)(d), (e), (f), (g), (h), (i) and (k) does not apply where-

(i) the Secretary of State decides that the provision of such particulars will be contrary to the interests of national security, or

(ii) suitable alternative arrangements have been agreed with the competent authority.";

(d) after subregulation (4) insert-

"(4A) The particulars in subregulation (4) are-

(a) the name, address, telephone number and email address of the employer;

(b) the address of the premises where or from where the work activity is to be carried out and a telephone number or email address for such premises;

(c) the nature of the business of the employer;

(d) a description of the work with ionising radiation;

(e) particulars of the source or sources of ionising radiation including the type of electrical equipment used or operated and the nature of any radioactive substance;

(f) the quantities of any radioactive substance used in the work;

(g) the identity of any person engaged in the work;

(h) whether or not any source is to be used at premises other than the address given in subparagraph (b);

(i) the location and description of any premises at which the work is carried out on each occasion that it is so carried out;

(j) the date of notification, registration or application for consent to carry out the work activity and the date of commencement of the work activity;

(k) the duration of any period over which the work is carried out and the date of termination of the work activity.";

(e) in subregulation (6) for "Regulation 26(9)" substitute "Regulation 24(6), (7) and (8), and 26(9)";

(f) in subregulation (7) for "sub-regulations (2) to (5) of regulation 7" substitute "regulations 7(2) to (5), and 16A(3)";

(g) after subregulation (7) insert-

"(7A) Regulation 23(4)(h) shall not apply in relation to-

(a) Her Majesty's Forces;

(b) visiting forces; or

(c) any member of a visiting force working in or attached to any headquarters or organisation.";

(h) in subregulation (8) for "sub-regulations (2) and (3) of regulation 13" substitute "regulation 13(2) and (3), and any provision of Part VIII".

(34) Regulation 53 is amended as follows-

(a) for subregulation (1) substitute-

"53.(1) Where on or before 5 February 2018 an employer commences for the first time, work which is required to be notified under regulation 7(2), it shall be sufficient compliance with that regulation if the employer notifies the competent authority and provides the particulars required by that provision on or before 5 February 2018.";

(b) for subregulation (2) substitute-

"(2) A contingency plan that was made prior to the 6 February 2018 and complied with the Ionising Radiation Regulations 2004 shall be treated, for the purposes of regulation 13, as if made pursuant to regulation 13(1).";

(c) after subregulation (2) insert-

"(2A) A person who has, before the 6 February 2018, obtained registration or authorisation to carry out a registrable practice or specified practice in accordance with regulations 6 or 6A, shall be deemed to have been granted authorisation under these Regulations.";

(d) in subregulation (3) for "regulation 15 of the 1995 Regulations and which is valid immediately before the date of coming into force of these Regulations" substitute "these Regulations prior to 6 February 2018";

(e) in subregulation (4) for "the Ionising Radiation (Outside Workers) Regulations 1995 and issued prior to the coming into force of these regulations" substitute "these Regulations and issued prior to 6 February 2018";

(f) in subregulation (5) for "the 1995 Regulations prior to the coming into force of these Regulations" substitute "these Regulations prior to 6 February 2018";

(g) subregulation (6) is deleted;

(h) in subregulation (7) for "regulation 16 of the 1995 Regulations prior to the coming into force of these Regulations" substitute "these Regulations prior to 6 February 2018";

(i) for subregulation (8) substitute-

"(8) An exemption certificate granted prior to 6 February 2018 shall continue in force until such time as it is revoked by the Government.";

(j) subregulation (9) is deleted.

(35) Regulation 55 is deleted.

(36) For Part VIII substitute-

"PART VIII

HIGH ACTIVITY SEALED SOURCES AND ORPHAN SOURCES

Authorisations for high-activity sealed sources.

56.(1) The competent authority may provide authorisation for any specified practice in regulation 6A which involves a high-activity sealed source.

(2) Before issuing an authorisation under subregulation (1) the competent authority shall ensure that-

(a) adequate arrangements have been made for the safety and control of sources, including when they become disused sources;

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

(3) The arrangements in subregulation (2)(a) may provide for-

(a) the transfer of disused sources to the supplier;

(b) the placement or storage of disused sources; or

(c) an obligation for the manufacturer or the supplier to receive disused sources.

(4) In addition to the general authorisation requirements set out in Part II, the authorisation for a practice involving a high-activity sealed source shall at least include-

(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;

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

(5) Subject to subregulation (6), each undertaking responsible for a high-activity sealed source shall keep records for such source that includes the information set out in Annex XIV of the Directive.

(6) The undertaking shall provide, upon request, to the competent authority an electronic or written copy of all or part of the records referred to in subregulation (5) and at least under the following conditions-

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

(b) at intervals to be determined by the competent authority;

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

(d) without undue delay upon the closure of the records for a specific source when the undertaking no longer holds this source, whereby the name of the

undertaking or waste disposal or storage facility to which the source is transferred shall be included;

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

Site security.

57.(1) Where the following material is, or will be, kept, used, disposed of or accumulated on any premises-

(a) high-activity sources; or

(b) other sealed sources which, in the opinion of the competent authority, are of a similar level of potential hazard to high-activity sources,

the competent authority, in considering if the measures taken, or to be taken, by the applicant or person granted the authorisation ensure the adequate security of any premises, shall where it, considers it appropriate–

(i) inspect those premises, and

(ii) consult with the police and such other persons as it, or he, considers appropriate concerning the measures.

(2) Where subregulation (1) applies, the competent authority shall have regard to any advice it receives from the police or other persons within such time as it believes is reasonable before–

(a) determining the authorisation or effecting any variation or cancellation of the authorisation; or

(b) imposing any limitations and conditions on the authorisation.

(3) Where the competent authority inspects any premises under subregulation (1) it may be accompanied by such other persons as are appropriate to assist it in assessing the measures.

(4) An applicant or person holding authorisation shall permit the competent authority, and any person accompanying them, reasonable access to any premises it wishes to inspect under subregulation (1).

(5) If an applicant or person holding authorisation fails to comply with subregulation (4), the competent authority may refuse the application or cancel or revoke the authorisation insofar as it relates to the sources referred to in subregulation (1).

Records and inspections.

58.(1) The competent authority shall keep records of any undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held.

(2) The records referred to in subregulation (1) shall include-

(a) the radionuclide involved;

(b) the activity at the time of manufacture or, if this activity is not known, the activity at the time of sale or at the time the undertaking acquired the source; and

(c) the type of source.

(3) The competent authority shall keep the records up to date, taking transfers of the sources and other factors into account.

Control of high-activity sealed sources.

59.(1) Each undertaking carrying out activities involving high-activity sealed sources 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, to be determined by the competent authority, 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 an appropriate authorisation;

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

(2) The manufacturer, the supplier, and each undertaking carrying out activities involving high-activity sealed sources shall ensure that the high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Schedule 14.

Detection of orphan sources.

60.(1) The competent authority shall ensure that arrangements are made, where appropriate, for-

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

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

(2) The competent authority shall ensure that specialised technical advice and assistance is promptly made available to persons who-

(a) are not normally involved in operations subject to radiation protection requirements; and

(b) suspect the presence of an orphan source.

(3) The competent authority shall ensure that the primary aim of the advice and assistance provided under subregulation (2) is-

(a) the safety of the source; and

(b) protecting the public and workers from radiation.

Metal contamination.

61. Any undertaking with responsibility for a metal scrap recycling installation shall ensure that it promptly informs the competent authority if it suspects or has knowledge of any melting of or other metallurgical operation on an orphan source and shall require that the contaminated materials are not-

(a) used;

(b) placed for sale; or

(c) disposed of without the involvement of the competent authority.

Recovery, management, control and disposal of orphan sources.

62.(1) The competent authority shall-

(a) be prepared, or have made provision, including the assignment of responsibilities, to control and recover any orphan sources;

(b) deal with emergencies due to orphan sources, having drawn up appropriate response plans and measures; and

(c) ensure that actions are taken to recover orphan sources left behind from past authorised practices.

(2) The competent authority may recover any expenses reasonably incurred by it in the recovery and disposal of an orphan source from-

(a) the person carrying on the radioactive substance activity involving that source; or

(b) the occupier or owner of the premises where the source is located.".

(37) For Schedule 1 substitute-

"**SCHEDULE 1**

WORK NOT REQUIRED TO BE NOTIFIED UNDER REGULATION 7

1. Work with ionising radiation is not required to be notified in accordance with regulation 7 when the only such work being carried out is in one or more of the following categories-

(a) where the concentration of activity per unit mass of a radioactive substance does not exceed the concentration specified in column 2 of Part 1 of Schedule 8 (for artificial radionuclides and naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties) or column 2 of Part 2 of Schedule 8 (for naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties);

(b) where the quantity of radioactive substance involved does not exceed the quantity specified in column 3 of Part 1 of Schedule 8 (for artificial radionuclides and naturally occurring radionuclides which are processed for their radioactive, fissile or fertile properties) or

column 3 of Part 2 of Schedule 8 (for naturally occurring radionuclides which are not processed for their radioactive, fissile or fertile properties);

(c) where the concentration of activity per unit mass or quantity of a radioactive substance does not exceed values which may be approved by the competent authority for specific types of work and where such work satisfies the exemption criteria set out in paragraphs 2 and 3 below;

(d) where apparatus contains radioactive substances in a quantity exceeding the values specified in subparagraphs (a) and (b) provided that-

(i) the apparatus is of a type approved by the competent authority,

(ii) the apparatus is constructed in the form of a sealed source,

(iii) the apparatus does not under normal operating conditions cause a dose rate of more than 1 μSvh-1 at a distance of 0.1 m from any accessible surface, and

(iv) conditions for the disposal of the apparatus have been specified by the competent authority;

(e) the operation of any electrical apparatus to which these Regulations apply other than apparatus referred to in subparagraph (f) provided that-

(i) the apparatus is of a type approved by the competent authority, and

(ii) the apparatus does not under normal operating conditions cause a dose rate of more than 1 μSvh-1 at a distance of 0.1 m from any accessible surface;

(f) the operation of-

(i) any cathode ray tube intended for the display of visual images, or

(ii) any other electrical apparatus operating at a potential difference not exceeding 30kV,

provided that the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1 μSvh^{-1} at a distance of 0.1 m from any accessible surface; or

(g) where the work involves contaminated material resulting from authorised releases which the competent authority has declared not to be subject to further control.

2. The criteria for the exemption from notification of work with ionising radiation are as follows-

(a) the radiological risks to individuals caused by such work are sufficiently low as to be of no regulatory concern;

(b) work of such type has been found to be justified; and

(c) such work is inherently safe.

3. Work with ionising radiation only meets the requirements of paragraph 2(a) if-

(a) in relation to an employee, the effective dose caused by such work does not exceed 1 mSv in a calendar year; and

(b) in relation to any other person, the following requirements are met in all circumstances where it is reasonably practicable to do so-

(i) the effective dose caused by such work from radionuclides which are not naturally occurring radionuclides does not exceed 10 µSv in a calendar year; and

(ii) the effective dose caused by such work from naturally occurring radionuclides does not exceed 1 mSv in a calendar year.".

(38) After Schedule 1 insert-

"**SCHEDULE 1A**

Consent to carry out a practice: indicative list of information

1. Responsibilities and organisational arrangements for protection and safety.

2. Staff competences, including information and training.

3. Design features of the facility and of radiation sources.

4. Anticipated occupational and public exposures in normal operation.

5. Safety assessment of the activities and the facility in order to-

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

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

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

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

6. Emergency procedures.

7. Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

8. Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.

9. Management of disused sources.

10. Quality assurance.".

(39) Schedule 4 is amended as follows-

(a) for the section-heading "Employees of 18 years of age or above" substitute "Employees and trainees of 18 years of age or above.";

(b) in paragraph 1 after "dose for any employee" insert "or trainee";

(c) for paragraph 2 substitute-

"2. Without prejudice to paragraph 1-

(a) the limit on equivalent dose for the lens of the eye is-

(i) 20 mSv in a calendar year, or

(ii) in accordance with conditions approved by the competent authority from time to time, 100 mSv in any period of five consecutive calendar years subject to a maximum equivalent dose of 50 mSv in any single calendar year;

(b) the limit on equivalent dose for the skin is 500 mSv in a calendar year as applied to the dose averaged over any area of 1 cm2 regardless of the area exposed;

(c) the limit on equivalent dose for the extremities is 500 mSv in a calendar year.";

(d) paragraph 4 is amended as follows-

(i) in subparagraph (a) for "shall be 50" substitute "is 15",

(ii) in subparagraph (b) for "shall be" substitute "is",

(iii) in subparagraph (c) for "hands, forearms, feet and ankles shall be" substitute "extremities is";

(e) paragraph 5 is deleted;

(f) paragraph 8 is amended as follows-

(i) in subparagraph (a) for "shall be" substitute "is",

(ii) in subparagraph (b) for "shall be" substitute "is",

(iii) in subparagraph (c) for "hands, forearms, feet and ankles shall be" substitute "extremities is";

(g) in paragraph 9 after "effective dose for employees" insert "or trainees";

(h) paragraph 10 is amended as follows-

(i) for subparagraph (a) substitute-

"(a) the limit on equivalent dose for the lens of the eye is-

(i) 20 mSv in a calendar year, or

(ii) in accordance with conditions approved by the competent authority from time to time, 100 mSv in any period of five consecutive calendar years subject to a maximum equivalent dose of 50 mSv in any single calendar year;",

(ii) in subparagraph (b) for "shall be" substitute "is",

(iii) in subparagraph (c) for "hands, forearms, feet and ankles shall be" substitute "extremities is";

(i) paragraph 11 is deleted;

(j) in paragraph 12 for "9 to 11" substitute "9 to 10";

(k) in paragraph 17 for "for a period of 50 years from the date of its making" substitute "until any person subject to that system of dose limitation has or would have attained the age of 75 years, but in any event for at least 30 years from the making of the record".

(40) In Schedule 5 at paragraph 1 after "supervised areas" insert "with a view to achieving an optimal level of protection for employees and members of the public".

(41) In Schedule 6 at paragraph 5 for "telex/fax number" substitute "e-mail address".

(42) In Schedule 7, paragraphs (d) and (h) are deleted.

(43) For Schedule 8 substitute-

"**SCHEDULE 8**

Quantities and concentrations of radionuclides

PART 1

Table of artificial radionuclides and naturally occurring radionuclides (which are processed for their radioactive, fissile or fertile properties)

1	2	3	4	5	6
Radionuclide name, symbol, isotope	**Concentration for: Notification (any amount of radioactive material); Registration (amounts of radioactive material that exceed 1,000kg)** **(Bq/g)**	**Quantity for Notification**	**Concentration for Registration (amounts of radioactive material that do not exceed 1,000kg)**	**Quantity for notification of occurrences**	**Quantity for notification of occurrences**

			(Bq/g)		
		(Bq)		(Bq)	(Bq)
Hydrogen					
H-3 (tritiated compounds)	10^2	10^9	10^6	10^{12}	10^{10}
Beryllium					
Be-7	10	10^7	10^3	10^{12}	10^8
Carbon					
C-11	0.01	10^6	10	10^{13}	10^7
C-11 (monoxide)	0.01	10^9	10	10^{12}	10^{10}
C-11 (dioxide)	0.01	10^9	10	10^{12}	10^{10}
C-14	1	10^7	10^4	10^{11}	10^8
Oxygen					
O-15	0.01	10^9	10^2	10^{10}	
Fluorine					
F-18	10	10^6	10	10^{13}	10^7
Sodium					
Na-22	0.1	10^6	10	10^{10}	10^7
Na-24	0.1	10^5	10	10^{11}	10^6
Silicon					
Si-31	10^3	10^6	10^3	10^{13}	10^7
Phosphorus					
P-32	10^3	10^5	10^3	10^{10}	10^6
P-33	10^3	10^8	10^5	10^{11}	10^9
Sulphur					
S-35	10^2	10^8	10^5	10^{11}	10^9
Chlorine					
Cl-36	1	10^6	10^4	10^{10}	10^7
Cl-38	10	10^5	10	10^{13}	10^6
Argon					
Ar-37	0.01	10^8	10^6	10^{13}	
Ar-41	0.01	10^9	10^2	10^9	
Potassium					
K-40[(1)]	1	10^6	10^2	10^{10}	10^7
K-42	10^2	10^6	10^2	10^{12}	10^7
K-43	10	10^6	10	10^{11}	10^7
Calcium					
Ca-45	10^2	10^7	10^4	10^{10}	10^8
Ca-47	10	10^6	10	10^{11}	10^7
Scandium					
Sc-46	0.1	10^6	10	10^{10}	10^7
Sc-47	10^2	10^6	10^2	10^{11}	10^7
Sc-48	1	10^5	10	10^{11}	10^6
Vanadium					
V-48	1	10^5	10	10^{10}	10^6

Chromium					
Cr-51	10^2	10^7	10^3	10^{12}	10^8
Manganese					
Mn-51	10	10^5	10	10^{13}	10^6
Mn-52	1	10^5	10	10^{10}	10^6
Mn-52m	10	10^5	10	10^{13}	10^6
Mn-53	10^2	10^9	10^4	10^{12}	10^{10}
Mn-54	0.1	10^6	10	10^{11}	10^7
Mn-56	10	10^5	10	10^{12}	10^6
Iron					
Fe-52+	10	10^6	10	10^{12}	10^7
Fe-55	10^3	10^6	10^4	10^{11}	10^7
Fe-59	1	10^6	10	10^{10}	10^7
Cobalt					
Co-55	10	10^6	10	10^{11}	10^7
Co-56	0.1	10^5	10	10^{10}	10^6
Co-57	1	10^6	10^2	10^{11}	10^7
Co-58	1	10^6	10	10^{10}	10^7
Co-58m	10^4	10^7	10^4	10^{13}	10^8
Co-60	0.1	10^5	10	10^{10}	10^6
Co-60m	10^3	10^6	10^3	10^{16}	10^7
Co-61	10^2	10^6	10^2	10^{13}	10^7
Co-62m	10	10^5	10	10^{13}	10^6
Nickel					
Ni-59	10^2	10^8	10^4	10^{11}	10^9
Ni-63	10^2	10^8	10^5	10^{11}	10^9
Ni-65	10	10^6	10	10^{13}	10^7
Copper					
Cu-64	10^2	10^6	10^2	10^{12}	10^7
Zinc					
Zn-65	0.1	10^6	10	10^{10}	10^7
Zn-69	10^3	10^6	10^4	10^{14}	10^7
Zn-69m+	10	10^6	10^2	10^{12}	10^7
Gallium					
Ga-68	0.01	10^5	10	10^{13}	10^6
Ga-72	10	10^5	10	10^{11}	10^6
Germanium					
Ge-68+	0.01	10^5	10	10^{10}	10^6
Ge-71	10^4	10^8	10^4	10^{13}	10^9
Arsenic					
As-73	10^3	10^7	10^3	10^{11}	10^8
As-74	10	10^6	10	10^{11}	10^7
As-76	10	10^5	10^2	10^{11}	10^6
As-77	10^3	10^6	10^3	10^{12}	10^7
Selenium					
Se-75	1	10^6	10^2	10^{11}	10^7
Bromine					
Br-82	1	10^6	10	10^{11}	10^7
Krypton					
Kr-74	0.01	10^9	10^2	10^9	

Kr-76	0.01	10^9	10^2	10^{10}	
Kr-77	0.01	10^9	10^2	10^9	
Kr-79	0.01	10^5	10^3	10^{10}	
Kr-81	0.01	10^7	10^4	10^{11}	
Kr-83m	0.01	10^{12}	10^5	10^{12}	
Kr-85	0.01	10^4	10^5	10^{12}	
Kr-85m	0.01	10^{10}	10^3	10^{10}	
Kr-87	0.01	10^9	10^2	10^9	
Kr-88	0.01	10^9	10^2	10^9	
Rubidium					
Rb-86	10^2	10^5	10^2	10^{11}	10^6
Strontium					
Sr-85	1	10^6	10^2	10^{11}	10^7
Sr-85m	10^2	10^7	10^2	10^{13}	10^8
Sr-87m	10^2	10^6	10^2	10^{13}	10^7
Sr-89	10^3	10^6	10^3	10^{10}	10^7
Sr-90+	1	10^4	10^2	10^9	10^5
Sr-91+	10	10^5	10	10^{12}	10^6
Sr-92	10	10^6	10	10^{12}	10^7
Yttrium					
Y-90	10^3	10^5	10^3	10^{11}	10^6
Y-91	10^2	10^6	10^3	10^{10}	10^7
Y-91m	10^2	10^6	10^2	10^{13}	10^7
Y-92	10^2	10^5	10^2	10^{12}	10^6
Y-93	10^2	10^5	10^2	10^{12}	10^6
Zirconium					
Zr-93+	10	10^7	10^3	10^9	10^8
Zr-95+	1	10^6	10	10^{10}	10^7
Zr-97+	10	10^5	10	10^{11}	10^6
Niobium					
Nb-93m	10	10^7	10^4	10^{11}	10^8
Nb-94	0.1	10^6	10	10^9	10^7
Nb-95	1	10^6	10	10^{11}	10^7
Nb-97+	10	10^6	10	10^{13}	10^7
Nb-98	10	10^5	10	10^{13}	10^6
Molybdenum					
Mo-90	10	10^6	10	10^{12}	10^7
Mo-93	10	10^8	10^3	10^{11}	10^9
Mo-99+	10	10^6	10^2	10^{11}	10^7
Mo-101+	10	10^6	10	10^{13}	10^7
Technetium					
Tc-96	1	10^6	10	10^{11}	10^7
Tc-96m	10^3	10^7	10^3	10^{14}	10^8
Tc-97	10	10^8	10^3	10^{12}	10^9
Tc-97m	10^2	10^7	10^3	10^{10}	10^8
Tc-99	1	10^7	10^4	10^{10}	10^8
Tc-99m	10^2	10^7	10^2	10^{13}	10^8
Ruthenium					
Ru-97	10	10^7	10^2	10^{12}	10^8
Ru-103+	1	10^6	10^2	10^{10}	10^7

Ru-105+	10	10^6	10	10^{12}	10^7
Ru-106+	0.1	10^5	10^2	10^9	10^6
Rhodium					
Rh-103m	10^4	10^8	10^4	10^{15}	10^9
Rh-105	10^2	10^7	10^2	10^{12}	10^8
Palladium					
Pd-103+	10^3	10^8	10^3	10^{11}	10^9
Pd-109+	10^2	10^6	10^3	10^{12}	10^7
Silver					
Ag-105	1	10^6	10^2	10^{11}	10^7
Ag-108m+	0.1	10^6	10	10^{10}	10^7
Ag-110m+	0.1	10^6	10	10^{10}	10^7
Ag-111	10^2	10^6	10^3	10^{11}	10^7
Cadmium					
Cd-109+	1	10^6	10^4	10^{10}	10^7
Cd-115+	10	10^6	10^2	10^{11}	10^7
Cd-115m+	10^2	10^6	10^3	10^{10}	10^7
Indium					
In-111	10	10^6	10^2	10^{11}	10^7
In-113m	10^2	10^6	10^2	10^{13}	10^7
In-114m+	10	10^6	10^2	10^{10}	10^7
In-115m	10^2	10^6	10^2	10^{13}	10^7
Tin					
Sn-113+	1	10^7	10^3	10^{11}	10^8
Sn-125	10	10^5	10^2	10^{10}	10^6
Antimony					
Sb-122	10	10^4	10^2	10^{11}	10^5
Sb-124	1	10^6	10	10^{10}	10^7
Sb-125+	0.1	10^6	10^2	10^{10}	10^7
Tellurium					
Te-123m	1	10^7	10^2	10^{10}	10^8
Te-125m	10^3	10^7	10^3	10^{10}	10^8
Te-127	10^3	10^6	10^3	10^{12}	10^7
Te-127m+	10	10^7	10^3	10^{10}	10^8
Te-129	10^2	10^6	10^2	10^{14}	10^7
Te-129m+	10	10^6	10^3	10^{10}	10^7
Te-131	10^2	10^5	10^2	10^{14}	10^6
Te-131m+	10	10^6	10	10^{11}	10^7
Te-132+	1	10^7	10^2	10^{11}	10^8
Te-133	10	10^5	10	10^{14}	10^6
Te-133m	10	10^5	10	10^{13}	10^6
Te-134	10	10^6	10	10^{13}	10^7
Iodine					
I-123	10^2	10^7	10^2	10^{12}	10^8
I-125	10^2	10^6	10^3	10^{10}	10^7
I-126	10	10^6	10^2	10^{10}	10^7
I-129	0.01	10^5	10^2	10^9	10^6
I-130	10	10^6	10	10^{11}	10^7
I-131	10	10^6	10^2	10^{10}	10^7
I-132	10	10^5	10	10^{12}	10^6

I-133	10	10^6	10	10^{11}	10^7
I-134	10	10^5	10	10^{13}	10^6
I-135	10	10^6	10	10^{12}	10^7
Xenon					
Xe-131m	0.01	10^4	10^4	10^{11}	
Xe-133	0.01	10^4	10^3	10^{11}	
Xe-135	0.01	10^{10}	10^3	10^{10}	
Caesium					
Cs-129	10	10^5	10^2	10^{12}	10^6
Cs-131	10^3	10^6	10^3	10^{12}	10^7
Cs-132	10	10^5	10	10^{11}	10^6
Cs-134	0.1	10^4	10	10^{10}	10^5
Cs-134m	10^3	10^5	10^3	10^{14}	10^6
Cs-135	10^2	10^7	10^4	10^{11}	10^8
Cs-136	1	10^5	10	10^{10}	10^6
Cs-137+	0.1	10^4	10	10^{10}	10^5
Cs-138	10	10^4	10	10^{13}	10^5
Barium					
Ba-131	10	10^6	10^2	10^{11}	10^7
Ba-140+	1	10^5	10	10^{11}	10^6
Lanthanum					
La-140	1	10^5	10	10^{11}	10^6
Cerium					
Ce-139	1	10^6	10^2	10^{11}	10^7
Ce-141	10^2	10^7	10^2	10^{10}	10^8
Ce-143	10	10^6	10^2	10^{11}	10^7
Ce-144+	10	10^5	10^2	10^9	10^6
Praseodymium					
Pr-142	10^2	10^5	10^2	10^{12}	10^6
Pr-143	10^3	10^6	10^4	10^{11}	10^7
Neodymium					
Nd-147	10^2	10^6	10^2	10^{11}	10^7
Nd-149	10^2	10^6	10^2	10^{13}	10^7
Promethium					
Pm-147	10^3	10^7	10^4	10^{10}	10^8
Pm-149	10^3	10^6	10^3	10^{11}	10^7
Samarium					
Sm-151	10^3	10^8	10^4	10^{10}	10^9
Sm-153	10^2	10^6	10^2	10^{11}	10^7
Europium					
Eu-152	0.1	10^6	10	10^9	10^7
Eu-152m	10^2	10^6	10^2	10^{12}	10^7
Eu-154	0.1	10^6	10	10^9	10^7
Eu-155	1	10^7	10^2	10^{10}	10^8
Gadolinium					
Gd-153	10	10^7	10^2	10^{10}	10^8
Gd-159	10^2	10^6	10^3	10^{12}	10^7
Terbium					
Tb-160	1	10^6	1	10^{10}	10^7
Dysprosium					

Dy-165	10^3	10^6	10^3	10^{13}	10^7
Dy-166	10^2	10^6	10^3	10^{11}	10^7
Holmium					
Ho-166	10^2	10^5	10^3	10^{11}	10^6
Erbium					
Er-169	10^3	10^7	10^4	10^{11}	10^8
Er-171	10^2	10^6	10^2	10^{12}	10^7
Thulium					
Tm-170	10^2	10^6	10^3	10^{10}	10^7
Tm-171	10^3	10^8	10^4	10^{11}	10^9
Ytterbium					
Yb-175	10^2	10^7	10^3	10^{11}	10^8
Lutetium					
Lu-177	10^2	10^7	10^3	10^{11}	10^8
Hafnium					
Hf-181	1	10^6	10	10^{10}	10^7
Tantalum					
Ta-182	0.1	10^4	10	10^{10}	10^5
Tungsten					
W-181	10	10^7	10^3	10^{12}	10^8
W-185	10^3	10^7	10^4	10^{11}	10^8
W-187	10	10^6	10^2	10^{12}	10^7
Rhenium					
Re-186	10^3	10^6	10^3	10^{11}	10^7
Re-188	10^2	10^5	10^2	10^{12}	10^6
Osmium					
Os-185	1	10^6	10	10^{11}	10^7
Os-191	10^2	10^7	10^2	10^{11}	10^8
Os-191m	10^3	10^7	10^3	10^{12}	10^8
Os-193	10^2	10^6	10^2	10^{11}	10^7
Iridium					
Ir-190	1	10^6	10	10^{10}	10^7
Ir-192	1	10^4	10	10^{10}	10^5
Ir-194	10^2	10^5	10^2	10^{11}	10^6
Platinum					
Pt-191	10	10^6	10^2	10^{11}	10^7
Pt-193m	10^3	10^7	10^3	10^{12}	10^8
Pt-197	10	10^6	10^3	10^{12}	10^7
Pt-197m	10^2	10^6	10^2	10^{14}	10^7
Gold					
Au-198	10	10^6	10^2	10^{11}	10^7
Au-199	10^2	10^6	10^2	10^{11}	10^7
Mercury					
Hg-197	10^2	10^7	10^2	10^{12}	10^8
Hg-197m	10^2	10^6	10^2	10^{12}	10^7
Hg-203	10	10^5	10^2	10^{11}	10^6
Thallium					
Tl-200	10	10^6	10	10^{11}	10^7
Tl-201	10^2	10^6	10^2	10^{12}	10^7
Tl-202	10	10^6	10^2	10^{11}	10^7
Tl-204	1	10^4	10^4	10^{11}	10^5

Lead					
Pb-203	10	10^6	10^2	10^{12}	10^7
Pb-210+	0.01	10^4	10	10^8	10^5
Pb-212+	1	10^5	10	10^{10}	10^6
Bismuth					
Bi-206	1	10^5	10	10^{10}	10^6
Bi-207	0.1	10^6	10	10^{10}	10^7
Bi-210	10	10^6	10^3	10^9	10^7
Bi-212+	1	10^5	10	10^{11}	10^6
Polonium					
Po-203	10	10^6	10	10^{13}	10^7
Po-205	10	10^6	10	10^{12}	10^7
Po-207	10	10^6	10	10^{12}	10^7
Po-210	0.01	10^4	10	10^7	10^5
Astatine					
At-211	10^3	10^7	10^3	10^{10}	10^8
Radon					
Rn-220+	0.01	10^7	10^4	10^8	10^8
Rn-222+	0.01	10^8	10	10^9	10^9
Radium					
Ra-223+	1	10^5	10^2	10^7	10^6
Ra-224+	1	10^5	10	10^8	10^6
Ra-225	10	10^5	10^2	10^7	10^6
Ra-226+	0.01	10^4	10	10^7	10^5
Ra-227	10^2	10^6	10^2	10^{13}	10^7
Ra-228+	0.01	10^5	10	10^8	10^6
Actinium					
Ac-228	1	10^6	10	10^{10}	10^7
Thorium					
Th-226+	10^3	10^7	10^3	10^{11}	10^8
Th-227	1	10^4	10	10^7	10^5
Th-228+	0.1	10^4	1	10^6	10^5
Th-229+	0.1	10^3	1	10^6	10^4
Th-230	0.1	10^4	1	10^6	10^5
Th-231	10^2	10^7	10^3	10^{12}	10^8
Th-232	0.01	10^4	10	10^6	10^5
Th-234+	10	10^5	10^3	10^{10}	10^6
Protactinium					
Pa-230	10	10^6	10	10^8	10^7
Pa-231	0.01	10^3	1	10^6	10^4
Pa-233	10	10^7	10^2	10^{10}	10^8
Uranium					
U-230+	10	10^5	10	10^7	10^6
U-231	10^2	10^7	10^2	10^{11}	10^8
U-232+	0.1	10^3	1	10^6	10^4
U-233	1	10^4	10	10^7	10^5
U-234	1	10^4	10	10^7	10^5
U-235+	1	10^4	10	10^7	10^5
U-236	10	10^4	10	10^7	10^5
U-237	10^2	10^6	10^2	10^{11}	10^7
U-238+	1	10^4	10	10^7	10^5

U-239	10^2	10^6	10^2	10^{14}	10^7
U-240	0.01	10^7	10^3	10^{12}	10^8
U-240+	10^2	10^6	10	10^{11}	10^7
Neptunium					
Np-237+	1	10^3	1	10^7	10^4
Np-239	10^2	10^7	10^2	10^{11}	10^8
Np-240	10	10^6	10	10^{13}	10^7
Plutonium					
Pu-234	10^2	10^7	10^2	10^{10}	10^8
Pu-235	10^2	10^7	10^2	10^{14}	10^8
Pu-236	1	10^4	10	10^7	10^5
Pu-237	10^2	10^7	10^3	10^{11}	10^8
Pu-238	0.1	10^4	1	10^6	10^5
Pu-239	0.1	10^4	1	10^6	10^5
Pu-240	0.1	10^3	1	10^6	10^4
Pu-241	10	10^5	10^2	10^8	10^6
Pu-242	0.1	10^4	1	10^6	10^5
Pu-243	10^3	10^7	10^3	10^{13}	10^8
Pu-244+	0.1	10^4	1	10^6	10^5
Americium					
Am-241	0.1	10^4	1	10^6	10^5
Am-242	10^3	10^6	10^3	10^{10}	10^7
Am-242m+	0.1	10^4	1	10^6	10^5
Am-243+	0.1	10^3	1	10^6	10^4
Curium					
Cm-242	10	10^5	10^2	10^7	10^6
Cm-243	1	10^4	1	10^7	10^5
Cm-244	1	10^4	10	10^7	10^5
Cm-245	0.1	10^3	1	10^6	10^4
Cm-246	0.1	10^3	1	10^6	10^4
Cm-247+	0.1	10^4	1	10^6	10^5
Cm-248	0.1	10^3	1	10^6	10^4
Berkelium					
Bk-249	10^2	10^6	10^3	10^9	10^7
Californium					
Cf-246	10^3	10^6	10^3	10^9	10^7
Cf-248	1	10^4	10	10^7	10^5
Cf-249	0.1	10^3	1	10^6	10^4
Cf-250	1	10^4	10	10^6	10^5
Cf-251	0.1	10^3	1	10^6	10^4
Cf-252	1	10^4	10	10^7	10^5
Cf-253	10^2	10^5	10^2	10^8	10^6
Cf-254	1	10^3	1	10^7	10^4
Einsteinium					
Es-253	10^2	10^5	10^2	10^8	10^6
Es-254+	0.1	10^4	10	10^7	10^5
Es-254m+	10	10^6	10^2	10^9	10^7
Fermium					
Fm-254	10^4	10^7	10^4	10^{10}	10^8
Fm-255	10^2	10^6	10^3	10^9	10^7
Other radionuclides not listed above (see Note 1)					

	0.01	10^3	0.1	10^5	10^4

Note 1

In the case of radionuclides not specified elsewhere in this Part, the quantities specified in this entry are to be used unless the Executivehas approved some other quantity for that radionuclide.

Note 2

Nuclides carrying the suffix "+" in the above table represent parent nuclides and their progeny as listed in the table below. The dose contributions for those progeny are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered).

([1]) Potassium salts in quantities less than 1,000kg are exempt.

List of parent nuclides and their progeny as referred to in Note 2 above

Parent radionuclide	Progeny
Fe-52	Mn-52m
Zn-69m	Zn-69
Ge-68	Ga-68
Sr-90	Y-90
Sr-91	Y-91m
Zr-93	Nb-93m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m

Parent radionuclide	Progeny
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144, Pr-144m
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208, Po-212

Parent radionuclide	Progeny
Bi-212	Tl-208, Po-212
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, Po-212
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, Po-212
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m
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, Po-212
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m, Np-240
Np-237	Pa-233
Pu-244	U-240, Np-240m, Np-240

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

PART 2

Table of naturally occurring radionuclides (which are not processed for their radioactive, fissile or fertile properties)

Values for exemption from notification and registration for naturally occurring radionuclides in solid materials (which are not processed for their radioactive, fissile or fertile properties), which apply whether or not the radionuclide is in secular equilibrium with its progeny.

1	2	3	4
Radionuclide name, symbol, isotope	***Concentration for: Notification (any amount of radioactive material); Registration (amounts of radioactive material that exceed 1,000kg)*** ***(Bq/g)***	***Quantity for Notification*** ***(Bq)***	***Concentration for Registration (amounts of radioactive material that do not exceed 1,000kg)*** ***(Bq/g)***
K-40[(1)]	10	10^6	10^2
Rb-87	1	10^7	10^4
Pb-210+	1	10^4	10
Po-210	1	10^4	10
Ra-226+	1	10^4	10
Ra-228+	1	10^5	10
Th-228+	1	10^4	1
Th-232 sec	1	10^3	1
U-238 sec	1	10^3	1
Note:			

Nuclides carrying the suffix "+" in the above table represent parent nuclides and their progeny as listed in the table below. The dose contributions of those progeny are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered).

(1) Potassium salts in quantities less than 1,000kg are exempt.

List of parent nuclides and their progeny as referred to in the Note above

Parent radionuclide	***Progeny***
Pb-210	Bi-210, Po-210
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212

PART 3

Quantity and concentration ratios for more than one radionuclide

1. For the purpose of Regulation 2(4)-

(a) the quantity ratio for more than one radionuclide is the sum of the quotients of the quantity of a radionuclide present Q_p divided by the quantity of that radionuclide specified in the appropriate entry in Parts 1, 2 or 4 of this Schedule Q_{lim}, namely-

$$\sum Q_p/Q_{lim}$$

(b) (the concentration ratio for more than one radionuclide is the sum of the quotients of the concentration of a radionuclide present C_p divided by the concentration of that radionuclide specified in the appropriate entry in Parts 1 or 2 of this Schedule C_{lim}, namely-

$$\sum C_p/C_{lim}$$

2. In any case where the isotopic composition of a radioactive substance is not known or is only partially known, the quantity or concentration ratio for that substance is to be calculated by using the values specified in the appropriate column in Part 1 of this Schedule for "other radionuclides not listed above" for any radionuclide that has not been identified or where the quantity or concentration of a radionuclide is uncertain, unless the employer can show that the use of some other value is appropriate in the circumstances of a particular case, when the employer may use that value.".

(44) For Schedule 9 substitute-

"**SCHEDULE 9**

Activity values defining high-activity sealed sources

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

Radionuclide Activity (TBq)	**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	

".

(45) Schedule 10 is deleted.

(46) After Schedule 10 insert-

"**SCHEDULE 11**

Radiation and tissue weighting factors

1. For the definition of "effective dose" at regulation 2-

$D_{T,R}$ 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 the tables below, and the unit for effective dose is the sievert (Sv).

2. For the definition of "equivalent dose" at regulation 2-

$D_{T,R}$ 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 table A below, and the unit for effective dose is the sievert (Sv).

Table 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 ≤ E n ≤ 50 MeV	$5{,}0 + 17{,}0\,e^{-[\ln(2\,En)]^2/6}$
Neutrons, E n > 50 MeV	$2{,}5 + 3{,}25\,e^{-[\ln(0{,}04\,En)]^2/6}$
Note: All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).	

Table 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

SCHEDULE 12

List of industrial sectors involving naturally-occurring radioactive material

When applying regulation 4A 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 13

Indicative list of types of existing exposure situations

(a) Exposure due to contamination of areas by residual radioactive material from-

(i) past activities that were never subject to regulatory control or were not regulated in accordance with the requirements laid down by the Directive,

(ii) an emergency, after the emergency exposure situation has been declared ended, as provided for in the off-site emergency response plan,

(iii) residues from past activities for which the undertaking is no longer legally accountable;

(b) Exposure to natural radiation sources, including-

(i) indoor exposure to radon and thoron, in workplaces, dwellings and other buildings,

(ii) indoor external exposure from building materials;

(c) Exposure to commodities excluding food, animal feeding stuffs and drinking water incorporating-

(i) radionuclides from contaminated areas specified in paragraph (a), or

(ii) naturally-occurring radionuclides.

SCHEDULE 14

Identification and marking of high-activity sealed sources

1. The manufacturer or supplier ensures that-

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

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

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

2. The manufacturer provides a photograph of each manufactured source design type and a photograph of the typical source container.

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

SCHEDULE 15

Reference levels for public exposure

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;

(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;

(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 16

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

1. Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and radium-226 content of rock or soil).

2. Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.

3. Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a 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 17

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

1. Natural materials

(a) Alum-shale.

(b) Building materials or additives of natural igneous origin, such as-

- granitoides (such as granites, syenite and orthogneiss),
- porphyries,
- tuff,
- pozzolana (pozzolanic ash),
- lava.

2. Materials incorporating residues from industries processing naturally occurring radioactive material, such as-

- fly ash;
- phosphogypsum;
- phosphorus slag;
- tin slag;
- copper slag;
- red mud (residue from aluminium production);
- residues from steel production.

SCHEDULE 18

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

For the purposes of regulation 16F(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 16F(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).".

Amendment of the Ionising Radiation (Administration of Radioactive Medicinal Products and Medical Exposures) Regulations 2002.

4.(1) The Ionising Radiation (Administration of Radioactive Medicinal Products and Medical Exposures) Regulations 2002 is amended in accordance with the provisions of this regulation.

(2) Regulation 2 is amended as follows-

(a) before the definition of "adequate training" insert-

""the 2004 Regulations" means the Ionising Radiation Regulations 2004;

"absorbed dose" has the same meaning as in the 2004 Regulations;

"accidental exposure" means an exposure of individuals as a result of an accident;

"activity" has the same meaning as in the 2004 Regulations;";

(b) after the definition of "clinical audit" insert-

""comforter and carer" means an individual who, other than as part of his occupation, knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or who has undergone any medical exposure;";

(c) for the definition of "diagnostic reference levels" substitute-

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

(d) for the definition of "dose constraint" substitute-

""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;";

(e) for the definition of "the Directive" substitute-

""the 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, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom;";

(f) after the definition of "the Directive" insert-

""effective dose" has the same meaning as in the 2004 Regulations;";

(g) in the definition of "employer" for the words "medical exposures" substitute "those exposures described in regulation 8";

(h) for the definition of "equipment" substitute-

""equipment" means equipment which-

(a) delivers ionising radiation to a person undergoing a medical exposure; or

(b) which directly controls or influences the extent of such exposure;";

(i) after the definition of "equipment" insert-

""equivalent dose" has the same meaning as in the 2004 Regulations;

"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);";

(j) in the definition of "health screening" for the words "ionising radiation" substitute "medical radiological installations";

(k) after the definition of "individual detriment" insert-

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

(l) for the definition of "medical exposure" substitute-

""medical exposure" means any exposure under paragraphs (a) to (e) of regulation 8;";

(m) in the definition of "medical physics expert" after the words "who is experienced" insert "to act or give advice";

(n) after the definition of "medical physics expert" insert-

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

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

(o) the definition of "medico-legal procedure" is deleted;

(p) after the definition of "the Minister" insert-

""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;";

(q) the definition of "notice" is deleted;

(r) for the definition of "occupational health surveillance" substitute-

> ""occupational health surveillance" 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 competent authority;";

(s) in the definition of "patient dose" for the word "exposure" substitute "exposures to which these Regulations apply";

(t) in the definition of "practical aspect" for the words "radioactive medicinal products and the development of films" substitute "radio-pharmaceuticals and image processing";

(u) the definition of "purpose" is deleted;

(v) for the definition of "quality assurance" substitute-

> ""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 and quality control;";

(w) after the definition of "quality control" insert-

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

(x) for the definition of "radioactive substance" substitute-

> ""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;";

(y) in the definition of "radiodiagnostic" after the words "diagnostic radiology" insert "using ionising radiation";

(z) in the definition of "radiological installation" for the words "containing equipment" substitute "where exposures to which these Regulations apply are performed";

(aa) after the definition of "radiotherapeutic" insert-

""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 a limit that may be exceeded;";

(bb) after the definition of "referrer" insert-

""Sievert" or "Sv" means the special name of the unit of equivalent or effective dose, and one sievert is equivalent to one joule per kilogram;

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

"unintended exposure" means any exposure to ionising radiation that is significantly different from the exposure intended for a given purpose;";

(cc) subregulation (3) is deleted.

(3) Regulation 8 is amended as follows-

(a) for paragraph (b) substitute-

"(b) the exposure of individuals as part of health screening programmes;";

(b) for paragraph (c) substitute-

"(c) the exposure of comforters and carers;";

(c) for paragraph (e) substitute-

"(e) the exposure of asymptomatic individuals;";

(d) after paragraph (e) insert-

"(f) the exposure of individuals undergoing non-medical imaging using medical radiological equipment.".

(4) Regulation 9 is amended as follows-

(a) in subregulation (2) after "each piece of equipment" insert ", including practices involving non-medical imaging";

(b) subregulation (3) is amended as follows-

(i) for paragraph (c) substitute-

"(c) regularly review and make available to an operator, diagnostic reference levels in respect of an exposure falling within-

(i) regulation 8(a)-

(aa) establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer,

(bb) where the exposure does not involve interventional radiology procedures, in which cases regard shall be had to European and national diagnostic reference levels where available,

(ii) regulation 8(b), or (e) in which cases regard shall be had to European and national diagnostic reference levels where available,

(iii) regulation 8(f) (non-medical imaging) where practicable;";

(c) for paragraph (d) substitute-

"(d) dose constraints-

(i) for biomedical and medical research programmes falling within regulation 8(d) where no direct health benefit is expected for the individual receiving the exposure, and

(ii) with regard to the protection of comforters and carers within regulation 8(c).";

(d) after subregulation (3) insert-

" (3A) A dose constraint shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.";

(e) after subregulation (7) insert-

" (8) The employer shall take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.".

(5) After regulation 9 insert-

"**Employer's duties re accidental or unintended exposure.**

9A.(1) The employer's procedures shall provide that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of a clinically significant unintended or accidental exposure and of the outcome of the analysis of this exposure.

(2) The employer's quality assurance programme shall, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposures.

(3) The employer shall establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice.

(4) Where the employer knows or has reason to believe that an accident or unintended exposure has or may have occurred in which a person, while undergoing an exposure was or could have been exposed to ionising radiation defined as significant, the employer shall-

(a) make an immediate preliminary investigation of the incident;

(b) unless that investigation shows beyond a reasonable doubt that no such exposure has occurred, immediately notify the Minister;

(c) conduct or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received; and

(d) notify the Minister of the outcome of the investigation and any corrective measures adopted, within the time period specified by the Minister.

Competent authority's duties re accidental and unintended exposure.

9B. The competent authority shall put in place mechanisms enabling the timely dissemination of information, relevant to radiation protection in respect of medical exposures, regarding lessons learned from significant events.".

(6) Regulation 11 is amended as follows-

(a) subregulation (1) is amended as follows-

(i) in paragraph (d) for "8(e)" substitute "8(f)",

(ii) in paragraph (e) for "." substitute "; and",

(iii) after paragraph (e) insert-

"(f) in the case of the administration of radioactive substances, the practitioner and employer are authorised to undertake the intended exposure.";

(b) for subregulation (3) substitute-

"(3) In considering the weight to be given to the matters referred to in subregulation (2), the practitioner justifying an exposure in accordance with subregulation (1)(b) shall have regard, in particular to-

(a) recommendations from appropriate medical scientific societies or relevant bodies where a procedure is to be performed as part of any health screening programme;

(b) whether in circumstances where there is to be an exposure to a comforter or carer such an exposure would show a sufficient net benefit taking into account-

(i) the likely direct health benefits to a patient,

(ii) the possible benefits to the comforter or carer, and

(iii) the detriment that the exposure might cause;

(c) in the case of asymptomatic individuals on whom any medical radiological procedure-

(i) is to be performed for the early detection of disease,

(ii) is to be performed as part of a health screening programme,

(iii) requires specific documented justification for that individual by the practitioner, in consultation with the referrer,

any guidelines issued by appropriate medical scientific societies, or relevant bodies;

(d) the urgency of the exposure, where appropriate, in cases involving-

(i) an individual where pregnancy cannot be excluded, in particular if abdominal and pelvic regions are involved, taking into account the exposure of both the person concerned and any unborn child, and

(ii) an individual who is breastfeeding and who undergoes an exposure involving the administration of radioactive substances, taking into account the exposure of both the individual and the child.".

(7) Regulation 12 is amended as follows-

(a) in subregulation (2) after "are individually planned," insert "their delivery appropriately verified,";

(b) in subregulation (3)(c) for "(c) and (e)" substitute "(e) and (f)";

(c) after subregulation (4) insert-

"(4A) In the case of regulation 8(c), the employer's procedures shall provide that appropriate guidance is established for the exposure of comforters and carers.";

(d) subregulation (7) is amended as follows-

(i) paragraph (a) is deleted,

(ii) in paragraph (e) before "medical exposures of females" insert "where appropriate,",

(iii) for paragraph (f) substitute-

"(f) where appropriate, medical exposures involving the administration of radioactive substances to individuals who are breastfeeding, taking into

account the exposure of both the individual and the child.",

(iv) in paragraph (8) after "exposure is recorded" insert "other than where the person subject to the exposure is a comforter or carer,",

(v) for paragraph (9) substitute-

"(9) The employer shall collect dose estimates from medical exposures for radiodiagnostic and interventional radiology purposes, taking into consideration, where appropriate, the distribution by age and gender of the exposed population and, when so requested, shall provide it to the Minister.".

(8) Regulation 14 is amended as follows-

(a) in subregulation (2)(b) after "nuclear medicine practices" insert ", high dose interventional radiology and high dose computed tomography";

(b) in subregulation (c)(ii) for "." substitute ", and";

(c) after subregulation (c) insert-

"(d) contribute in particular to matters specified in Schedule 3.".

(9) Regulation 15 is amended as follows-

(a) for subregulation (1) substitute-

"(1) An employer who has control over any equipment shall-

(a) implement and maintain a quality assurance programme in respect of that equipment which shall as a minimum permit-

(i) the assessment of the dose of ionising radiation that a person may be exposed to from

an exposure described in regulation 8, by way of the ordinary operation of that equipment, and

(ii) the administered activity to be verified;

(b) draw up, keep up-to-date and preserve, an inventory of the radiological equipment kept at each radiological installation, and when so requested, furnish such inventory to the Minister;

(c) ensure that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection.";

(b) for subregulation (3) substitute-

"(3) An employer shall undertake adequate-

(a) testing of any equipment before it is first used for a medical radiological purpose;

(b) performance testing at regular intervals;

(c) performance testing following a maintenance procedure which is capable of affecting the equipment's performance.";

(c) after subregulation (3) insert-

"(4) No person is permitted to use fluoroscopy equipment unless that equipment features-

(a) a device to control automatically the dose rate; or

(b) an image intensifier or equivalent device.

(5) Equipment used for interventional radiology and computed tomography shall have a device or other feature capable of informing the practitioner, at the end of an exposure, of relevant parameters for assessing the patient dose.

(6) An employer shall-

(a) take steps to put in place any measures necessary to improve inadequate or defective performance of equipment;

(b) specify acceptable performance criteria for equipment; and

(c) specify what corrective action is necessary when, further to the application of any criteria specified under paragraph (b), equipment is ascertained to be defective, and such corrective action may include taking the equipment out of service.

Equipment installed on or after 6 February 2018.

15A.(1) This regulation only applies in respect of-

(a) equipment installed on or after 6 February 2018; and

(b) an employer who has control of any such equipment.

(2) Equipment used for external beam radiotherapy with a nominal beam exceeding 1 MeV shall have a device, or other feature, the purpose of which is, to verify key treatment parameters.

(3) Equipment used for interventional radiology shall have a device or other feature capable of informing any person involved in the conduct of an exposure of the amount of radiation produced by the equipment during such an exposure.

(4) Equipment used for planning, guiding and verification purposes, shall have a device or other feature capable of informing the practitioner, at the end of an exposure, of relevant parameters for assessing the dose.

(5) Equipment used for interventional radiology and computed tomography shall have the capacity to transfer, to the record of a person's examination, information relating to relevant parameters for assessing the dose.

(6) Insofar as not already provided in this regulation, any equipment producing ionising radiation shall-

(a) have a device, or other feature, capable of informing the practitioner of relevant parameters for assessing the patient dose; and

(b) where appropriate, have the capacity to transfer this information to the record of a person's examination.".

(10) Schedule 1 is amended as follows-

(a) in paragraph (b) after "practitioner or operator" insert "within a specified scope of practice";

(b) paragraph (c) is deleted;

(c) in paragraph (e) for "are followed" substitute "in respect of written procedures, written protocols, and equipment are followed";

(d) for paragraph (g) substitute-

"(g) procedures for the use and review of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 8(a), (b), (e) and (f);";

(e) in paragraph (h) after "is required to effect one or" insert "more of the";

(f) in paragraph (j) the last "and" is deleted;

(g) in paragraph (k) for "." substitute ";";

(h) after paragraph (k) insert-

"(l) procedures providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;

(m) procedures to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure;

(n) procedures to be observed in the case of non-medical imaging exposures; and

(o) procedures to establish appropriate dose constraints and guidance for the exposure of comforters and carers.".

(11) For Schedule 2 substitute-

"**SCHEDULE 2**

Adequate training

1. Practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience, in-

(a) such of the subjects detailed in Table 1 as are relevant to their functions as practitioner or operator; and

(b) such of the subjects detailed in Table 2 as are relevant to their specific area of practice.

Table 1 – Radiation production, radiation protection and statutory obligations relating to ionising radiations

Fundamental Physics of Radiation

Properties of Radiation	Excitation and ionisation

	Attenuation of ionising radiation
	Scattering and absorption
Radiation Hazards and dosimetry	Biological effects of radiation - stochastic and deterministic
	Risks and benefits of radiation
	Absorbed dose, equivalent dose, effective dose, other dose indicators and their units

Management and Radiation Protection of the individual being exposed

Special Attention Areas	Pregnancy and potential pregnancy
	Asymptomatic individuals
	Breastfeeding
	Infants and children
	Medical and biomedical research
	Health screening
	Non-medical imaging
	Carers and comforters
	High dose techniques
Justification	Justification of the individual exposure
	Use of existing appropriate radiological information
	Alternative techniques
Radiation Protection	Diagnostic reference levels
	Dose Constraints
	Dose Optimisation
	Dose reduction devices and techniques
	Dose recording and dose audit
	General radiation protection

	Quality Assurance and Quality Control including routine inspection and testing of equipment
	Risk communication
	Use of radiation protection devices
Statutory Requirements and Non-Statutory Regulations	
	Regulations
	Non-statutory guidance
	Local procedures and protocols
	Individual responsibilities relating to exposures
	Responsibility for radiation safety
	Clinical audit

Table 2 - Diagnostic radiology, radiotherapy and nuclear medicine

All Modalities	
General	Fundamentals of radiological anatomy
	Factors affecting radiation dose
	Dosimetry
	Fundamentals of clinical evaluation
	Identification of the individual being exposed
Diagnostic radiology	
General	Principles of radiological techniques
	Production of X-rays
	Equipment selection and use
Specialised Techniques	Computed Tomography – advanced applications
	Interventional procedures

	Cone Beam Computed Tomography Hybrid imaging
Fundamentals of Image Acquisition etc.	Optimisation of image quality and radiation dose Image formats, acquisition, processing, display and storage
Contrast Media	Use and preparation Contra-indications Use of contrast injection systems
Radiotherapy	
General	Production of ionising radiation Treatment of malignant disease Treatment of benign disease Principles of external beam radiotherapy Principles of brachytherapy
Specialised techniques	Intra-operative radiotherapy Stereotactic radiotherapy and radiosurgery Stereotactic ablative radiotherapy Proton therapy MR Linac therapy
Radiobiological Aspects for Radiotherapy	Fractionation Dose rate Radiosensitisation Target volumes
Practical Aspects for Radiotherapy	Localisation equipment selection Therapy equipment selection

	Verification techniques including on-treatment imaging
	Treatment planning systems
Radiation Protection Specific to Radiotherapy	Side effects—early and late
	Toxicity
	Assessment of efficacy
Nuclear Medicine	
General	Atomic structure and radioactivity
	Radioactive decay
	Principles of molecular imaging and non-imaging exposures
	Principles of molecular radiotherapy
Molecular Radiotherapy	Dose rate
	Fractionation
	Radiobiology aspects
	Radiosensitisation
Specialised techniques	Quantitative imaging – advanced applications
	Hybrid imaging – advanced applications
	Selective Internal Radiation Therapy
Principles of Radiation Detection, Instrumentation and Equipment	Types of detection systems
	Optimisation of image quality and radiation dose
	Image acquisition, artefacts, processing, display and storage
Radiopharmaceuticals	Calibration
	Working practices in the radiopharmacy

	Preparation of individual doses
Radiation Protection Specific to Nuclear Medicine	Conception, pregnancy and breastfeeding
	Arrangements for radioactive individuals

".

(12) After Schedule 2 insert-

"**SCHEDULE 3**

Medical Physics Expert

1. The matters specified in this Schedule are-

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

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

(c) acceptance testing of equipment;

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

(e) the surveillance of the medical radiological installations;

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

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

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

(i) the provision of advice to an employer relating to compliance with these Regulations;

(j) the medical physics expert is, where appropriate, to liaise with and radiation protection supervisor under the 2004 Regulations.".

Amendment of the Radiation (Emergency Preparedness and Public Information) Regulations 2004.

5.(1) The Radiation (Emergency Preparedness and Public Information) Regulations 2004 is amended in accordance with the provisions of this regulation.

(2) For every instance of "emergency plan" substitute "emergency response plan".

(3) Regulation 2 is amended as follows-

(a) for the definition of "approved dosimetry service" substitute-

""approved dosimetry service" has the same meaning as in the 2004 Regulations;";

(b) after the definition of "approved dosimetry service" insert-

""Bq" means Becquerel, which is the special name of the unit of activity, and one Becquerel is equivalent to one nuclear transition per second;";

(c) after the definition of "consignor" insert-

""contamination" means the unintended and undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body, and "contaminated" is to be construed accordingly;";

(d) in the definitions of "dose assessment" and "dose record" for "22" substitute "23";

(e) after the definition of "dose record" insert-

""effective dose" has the same meaning as in the 2004 Regulations;

"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;";

(f) for the definition of "emergency exposure" substitute-

""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;";

(g) after the definition of "emergency services" insert-

""emergency 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 the 2004 Regulations and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

"equivalent dose" has the same meaning as in the 2004 Regulations;

"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;

"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;";

(h) after the definition of "Health Authority" insert-

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

(i) after the definition of "ionising radiation" insert-

""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;";

(j) in the definition of "medical surveillance" for "25" substitute "26";

(k) for the definition of "member of the public" substitute-

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

(l) after the definition of "the Minister" insert-

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

(m) for the definition of "practice" substitute-

""practice" means work involving-

(a) the production, processing, handling, use, holding, storage, transport or disposal of radioactive substances; or

(b) the operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5kV,

which can increase the exposure of individuals to ionising radiation;";

(n) after the definition of "premises" insert-

""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;";

(o) the definitions of "radiation accident" and "radiation emergency" are deleted;

(p) before the definition of "radioactive substance" insert-

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

"radioactive material" means material incorporating radioactive substances;";

(q) in the definition of "radioactive substance" after "radionuclides whose activity" insert "or activity concentration";

(r) after "radioactive substance" insert-

""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 a limit that may be exceeded;

"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;";

(s) for the definition of "sealed source" substitute-

""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;";

(t) after the definition of "sealed source" insert-

""Sievert" or "Sv" means the special name of the unit of equivalent or effective dose, and one sievert is equivalent to one joule per kilogram;

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

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

(u) for the definition of "work with ionising radiation" substitute-

""work with ionising radiation" means work or a practice under the 2004 Regulations.";

(v) subregulation (4) is deleted.

(4) Regulation 3 is amended as follows-

(a) for subregulation (1) substitute-

"3.(1) Subject to subregulation (4), these Regulations shall apply to any work with ionising radiation that falls within the application of the 2004 Regulations.";

(b) subregulations (2) and (3) are deleted.

(5) Regulation 4 is amended as follows-

(a) in subregulation (1)(c) for "a radiation accident" substitute "an emergency";

(b) in subregulation (2) for "radiation accident" substitute "emergency".

(6) For regulation 7(3) substitute-

"(3) Without prejudice to the generality of subregulation (1), the operator's emergency response plan shall include-

(a) the elements defined in Schedule 7;

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

(c) where appropriate, incorporate relevant elements of the off-site emergency response plan at Schedule 8.".

(7) For regulation 8(3) substitute-

"(3) Without prejudice to the generality of subregulation (1), the carrier's emergency response plan shall include-

(a) the elements defined in Schedule 7;

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

(c) where appropriate, incorporate relevant elements of the off-site emergency response plan at Schedule 8.".

(8) Regulation 9 is amended as follows-

(a) after subregulation (1) insert-

"(1A) When developing an off-site emergency response plan under subregulation (1) the Environmental Agency shall keep in mind that emergencies that occur outside of Gibraltar may still affect Gibraltar.";

(b) for subregulation (2) substitute-

"(2) Without prejudice to the generality of subregulation (1), the off-site emergency response plan shall-

(a) include the elements listed in Schedule 8;

(b) be designed to be commensurate with the results of an assessment of potential emergency exposure situations and to be able to respond effectively to emergency exposure situations in connection with practices or unforeseen events; and

(c) provide for the establishment of emergency response plans with the objective of avoiding tissue reactions leading to severe deterministic effects in any individual from the affected population and reducing the risk of stochastic effects, taking account of the general principles of radiation protection and the reference levels referred to in the 2004 Regulations.".

(9) Regulation 10 is amended as follows-

(a) in subregulation (2)(d) "and" is deleted;

(b) in subregulation (2)(e) for "." substitute ";";

(c) after subregulation (2)(e) insert-

"(f) any past emergency exposure situations and lessons learned.".

(10) Regulation 13 is amended as follows-

(a) after subregulation (1) insert-

"(1A) Where a radiation emergency occurs, the operator or carrier shall take all appropriate action to reduce the consequences.";

(b) after subregulation (2) insert-

"(2A) In the event of an emergency, the Government's Civil Contingency Committee, where appropriate, shall-

(a) require that the oganisation takes appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Schedule 7;

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

(c) ensure, if the situation so requires, that provision is made to organise the medical treatment of those affected.";

(c) subregulation (3) is amended as follows-

(i) in paragraph (b) the last "and" is deleted,

(ii) in paragraph (c) for "." substitute ";",

(iii) after paragraph (c) insert-

"(d) that steps are taken to provide assistance with protective measures; and

(e) provision for protective measures with regard to-

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

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

(iii) individuals, to reduce their exposure.";

(d) in subregulation (4)(d) for "50" substitute "30".

(11) Regulation 14 is amended as follows-

(a) for every instance of "emergency exposure" substitute "emergency exposure situation";

(b) for every instance of "emergency exposures" substitute "emergency exposure situations";

(c) in subregulation (10) for "50" substitute "30".

(12) For regulation 15 substitute-

"**Disapplication of dose limits.**

15.(1) In the event of an emergency, regulation 12 (dose limitation) of the 2004 Regulations shall not apply to intervention.

(2) Subject to subregulation (3), the employers shall ensure that emergency occupational exposures remain, wherever possible, below the values of the dose limits laid down in regulation 12 of the 2004 Regulations.

(3) For situations where the condition in subregulation (2) is not feasible the following exposure levels shall apply-

(a) the limit on effective dose shall not exceed 100 mSv;

(b) in exceptional circumstances, such as in order to-

(i) saves lives,

(ii) prevent severe radiation-induced health effects, or

(iii) prevent the development of catastrophic conditions,

the limit on the effective dose from external radiation of emergency workers shall not exceed 500 mSv.

(4) An employer of an emergency worker who is liable to undertake actions whereby an effective dose of 100 mSv may be exceeded shall clearly and comprehensibly inform the emergency worker in advance of-

(a) the associated health risks; and

(b) the available protection measures,

and the emergency worker shall undertake these actions voluntarily.

(5) In the event of an emergency occupational exposure-

(a) the employer shall ensure that radiological monitoring of the emergency workers is undertaken, and the individual monitoring or assessment of individual doses shall be carried out as appropriate to the circumstances;

(b) the employer shall ensure that special medical surveillance of emergency workers, in accordance with regulation 26 of the 2004 Regulations, is carried out as appropriate to the circumstances.".

(13) Schedules 1 to 4 are deleted.

(14) For Schedule 7 substitute-

"**SCHEDULE 7**

Elements to be included in an emergency response plan

For emergency preparedness:

1. Reference levels for public exposure, taking into account the criteria laid down in Schedule 15 of the 2004 Regulations;

2. Reference levels for emergency occupational exposure taking into account regulation 15;

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.".

(15) For Schedule 8 substitute-

"**SCHEDULE 8**

Elements to be included in the off-site emergency response plan

1. Assessment of potential emergency exposure situations and associated public and emergency occupational exposures;

2. Clear allocation of the responsibilities of persons and organisations having a role in preparedness and response arrangements;

3. Establishment of emergency response plans at appropriate levels and related to a specific facility or human activity;

4. Reliable communications and efficient and effective arrangements for cooperation and coordination at the installation and at appropriate national and international levels;

5. Health protection of emergency workers;

6. Arrangements for the provision of prior information and training for emergency workers and all other persons with duties or responsibilities in emergency response, including regular exercises;

7. Arrangements for individual monitoring or assessment of individual doses of emergency workers and the recording of doses;

8. Public information arrangements;

9. Involvement of stakeholders;

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

Consequential amendments.

6.(1) In regulation 2 of the Pollution Prevention and Control Regulations 2013, for paragraph (a) of the definition of "substance" substitute-

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

(2) In Schedule 2 of the Environment (Waste) Regulations 2007, for the paragraph beginning "-components containing radioactive substances" substitute-

"-components containing radioactive substances with the exception of components that are below the exemption thresholds set in Annex VII of Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom; and".

(3) In regulation 2 of the Transfrontier Shipment of Radioactive Waste and Spent Fuel Regulations 2012, for the definition of "practice" substitute-

""practice" means a human activity which can increase the exposure of individuals to ionising radiation;".

(4) After regulation 2(2) of the Management of Health and Safety at Work Regulations, 1996 insert-

"(3) For the purposes of these Regulations-

(a) the word "work" shall include any instruction or training which a person undergoes as a trainee and the meaning of "at work" shall be construed accordingly; and

(b) a trainee shall, while he is undergoing instruction or training in respect of work with ionising radiation, be treated as the employee of the person whose undertaking (whether for profit or not) is providing that instruction or training and that person shall be treated as the employer of that trainee except that the duties to the trainee imposed upon the person providing instruction or training shall only extend to matters under the control of that person.".

Dated 25th January, 2018.

DR J CORTES,
For the Government.

EXPLANATORY MEMORANDUM

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