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I. GENERAL PROVISIONS

MINISTRY OF THE PRESIDENCY, RELATIONS WITH THE COURTS AND DEMOCRATIC MEMORY

21682 *Royal Decree 1029/2022 of 20 December, approving the Regulation on health protection against the dangers arising from exposure to ionising radiation.*

I

Article 2.b) of the Treaty establishing the European Atomic Energy Community (hereinafter referred to as Euratom) requires the Community to establish uniform safety standards to protect the health of workers and of the general public and to ensure that they are applied. Article 30 of this treaty states that basic standards shall be laid down for the protection of the health of workers and the general public against the dangers arising from ionising radiation. These basic standards shall be aimed at identifying the maximum permissible doses compatible with adequate safety, the maximum permissible levels of contamination and the fundamental principles of medical surveillance of workers.

In order to perform its task, the Community first laid down basic standards by means of the Directives of 2 February 1959, which set out the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. These directives have been revised several times,–most recently by Council Directive 96/29/Euratom . the one prior to the one partially transposed by this Royal Decree laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, which repealed the Directive of 2 February 1959, the Directive of 5 March 1962 and Directives 66/45/Euratom, 76/579/Euratom, 80/836/Euratom and 84/467/Euratom with effect from 13 May 2000.

Council Directive 96/29/Euratom of 13 May 1996 laid down the basic safety standards applying to normal and emergency situations and was supplemented by more specific legislation in the following directives:

Council Directive 97/43/Euratom of 30 June 1997 on health protection against the dangers of ionising radiation in relation to medical exposure, repealing Directive 84/466/Euratom.

Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers potentially exposed to ionising radiation when working in a controlled area.

Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources.

Consequently, the Council of the European Union has issued successive provisions of obligatory compliance for the Member States, derived from the aforementioned Article 2.b) of the Euratom Treaty, which have been incorporated into Spanish law. The Regulation on health protection against ionising radiation, approved by Royal Decree 783/2001 of 6 July 2001, was the regulation which mainly transposed

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Council Directive 96/29/Euratom of 13 May 1996, while clarifying, developing and supplementing the provisions of Chapter VI of Law 25/1964 of 29 April 1964 on nuclear energy, concerning safety measures and protection against ionising radiation.

In addition, the other directives mentioned above were transposed in the following regulations:

Council Directive 97/43/Euratom of 30 June 1997 in Royal Decree 815/2001 of 13 July 2001 on the justification of the use of ionising radiation for the radiological protection of individuals during medical exposure.

Council Directive 89/168/Euratom of 27 November 1989, in the Resolution of 20 October 1999, providing for the publication of the Agreement reached by the Cabinet on 1 October 1999 in relation to public information on applicable health protection measures and the way to proceed in the event of a radiological emergency.

Council Directive 90/641/Euratom of 4 December 1990 in Royal Decree 413/1997 of 21 March 1997 on the operational protection of outside workers at risk of exposure to ionising radiation due to intervention in a controlled area.

Council Directive 2003/122/Euratom of 22 December 2003 in Royal Decree 229/2006 of 24 February 2006 on the control of high-activity encapsulated radioactive sources and orphan sources.

II

On 5 December 2013, the Council of the European Union adopted 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.

This Directive takes into account, in the basic safety standards, the recommendations of the International Commission on Radiological Protection, in particular those of its Publication 103, differentiating between existing, planned and emergency exposure situations. Accordingly, this Directive is intended to cover all exposure situations and all categories of exposure, namely occupational, members of the public and medical exposures.

Regardless of this new approach, Council Directive 2013/59/Euratom of 5 December 2013 continues to use the previous concepts of
"practices" and interventions".

The commitment to comply with the provisions of the aforementioned Council Directive 2013/59/Euratom, of 5 December 2013, which imposes on all the Member States of the European Union the obligation to have in force the legal, regulatory and administrative provisions required for its transposition, has made it necessary to approve a new regulatory text which, together with other provisions that may have an impact in this area, contemplates the basic radiation protection standards applicable systematically and under the principles of justification, optimisation and, where appropriate, dose limitation, and which repeals Royal Decree 783/2001, of 6 July, approving the Regulation on health protection against ionising radiations.

This Royal Decree partially transposes Council Directive 2013/59/Euratom of 5 December 2013 on health protection against the dangers arising from exposure to ionising radiation. This Royal Decree has been drawn up in accordance with the principles of good regulation set out in article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, and its content is in line with these principles.

In this sense, the administrative burdens and new obligations incorporated by this Royal Decree are those strictly necessary and proportional for the

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aim to achieve its objectives and to transpose Council Directive 2013/59/Euratom of 5 December 2013 into national law, thus acting in accordance with the principles of proportionality and efficiency.

Furthermore, in accordance with the principles of necessity and effectiveness, the regulation of health protection against the dangers arising from exposure to ionising radiation is in the general interest, with a positive impact on the protection of people and the environment.

Likewise, in accordance with the principle of legal certainty, the regulation is consistent with the existing national regulations on protection against ionising radiation, which it partly replaces in order to adapt the national legal system to the new European requirements, and with the European Union regulations on the same subject, which it is intended to adapt, as it incorporates the aforementioned Council Directive 2013/59/Euratom of 5 December 2013 into Spanish law.

Finally, in the drafting of this Royal Decree, the sectoral and social economic agents concerned and the Autonomous Communities have been consulted, in accordance with the principle of transparency, and it has been submitted, in its draft phase, to the prior public consultation, hearing and public information procedures, in accordance with the provisions of Law 50/1997, of 27 November, on the Government.

III

This Royal Decree, whose scope of application is similar to that of Royal Decree 783/2001, of 6 July, which it repeals, incorporates the precepts established in Royal Decree 413/1997, of 21 March, on the operational protection of outside workers at risk of exposure to ionising radiation due to intervention in a controlled area, which is likewise repealed. This ensures that external outside workers receive the same protection as exposed workers employed by a company practising with radiation sources.

In relation to external exposure, the methodology set out in Publication 116 of the International Commission on Radiological Protection is incorporated. On the other hand, in relation to internal exposure, the provisions of the Commission's Publication 103 are taken into consideration.

The current effective dose limits are maintained for apprentices and members of the public, but not for occupational exposures, where averaging over five years is no longer permitted to ensure compliance with the limits, except in specified special circumstances.

The equivalent dose limit for the eye lens for occupational exposure is reduced.

Protection against natural radiation sources, instead of being dealt with separately under a specific heading, is fully integrated into the overall requirements. In particular, industries processing materials containing naturally occurring radionuclides should be managed within the same regulatory framework as other practices.

In relation to protection against radon, it establishes the Government's obligation to promote and approve a National Action Radon Plan, for addressing the long-term risks from radon exposure. It also establishes the reference level for indoor radon concentration and specifies the obligations regarding compliance with this level, as well as, in the case of occupational exposures to radon, the annual dose level above which the exposure of workers is to be managed as a planned exposure situation.

It also establishes a reference level for indoor exposure to gamma radiation emitted by building materials, including a list of the types of materials that require monitoring to ensure compliance with this level.

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The exposure of aircraft and spacecraft crew personnel to cosmic radiation is considered as an existing exposure situation which is managed as a planned exposure situation.

The deliberate addition of radioactive substances to certain categories of consumer products remain prohibited

The deliberate exposure of individuals for non-medical imaging is prohibited, except where such practices have been expressly justified and authorised.

The general principles relating to interventions are established and new reference levels associated with emergency exposure situations are introduced, both for emergency intervention personnel and for members of the public, in order to deepen the principle of optimisation, with other aspects relating to these situations being regulated in the regulations derived from Law 17/2015, of 9 July, on the National Civil Protection System.

The roles and responsibilities of the radiation protection experts and services providing specific radiation protection advice and carrying out the radiation protection functions assigned to them are clarified.

IV

This Royal Decree is issued under the provisions of Article 149.1.16., 7., 23., 29., 10. and 20. of the Spanish Constitution, which grants the State exclusive competence in matters of general coordination of health, labour legislation, basic legislation on environmental protection, public safety, foreign trade and air traffic and transport, respectively.

During its preparation, in addition to the aforementioned consultations in accordance with the principle of transparency, the reports of the Interterritorial Council of the National Health System, the National Commission for Health and Safety at Work and the National Council for Civil Protection have been obtained.

Likewise, this Royal Decree has been drawn up by virtue of Article 94 of Law 25/1964, of 29th April, on nuclear energy, which authorises the Government "to establish the Regulations necessary for its application and development", having been favourably reported by the Nuclear Safety Council.

Finally, it should be pointed out that the project covering the present provision has been reported to the European Commission in accordance with what is set out in Article 33 of the Treaty establishing the European Atomic Energy Community (Euratom).

By virtue thereof, at the proposal of the Minister for Ecological Transition and the Demographic Challenge, the Minister of the Interior, and the Ministers of Transport, Mobility and the Urban Agenda, Labour and the Social Economy, and Health, with the prior approval of the Minister of Finance and the Civil Service, in agreement with the Council of State, and following deliberation by the Council of Ministers at its meeting of 20 December 2022,

PROVIDED:

Sole Article. *Approval of the regulation.*

The Regulation on health protection against dangers arising from exposure to ionising radiation, the text of which is set out below, is hereby approved.

Sole additional provision. *References to the Regulation on health protection against ionising radiations, approved by Royal Decree 783/2001, of 6 July.*

Normative references made in other provisions to the Regulation on health protection against ionising radiation, approved by Royal Decree 783/2001,

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of 6 July, shall be understood to be made to the corresponding precepts of the regulations approved by this Royal Decree.

Sole derogatory Provision. *Annulment of Standards.*

Royal Decree 783/2001, of 6 July 2001, approving the Regulation on health protection against ionising radiation, and Royal Decree 413/1997, of 21 March 1997, on the operational protection of outside workers at risk of exposure to ionising radiation due to intervention in a controlled area, are hereby repealed, as are all regulations of equal or lower rank that contradict or oppose the provisions of this Royal Decree and the attached regulation.

First final provision. *Amendment of the Regulation on the installation and use of X-ray equipment for medical diagnostic purposes, approved by Royal Decree 1085/2009 of 3 July 2009.*

Paragraphs 4 and 5 of Article 12 of the Regulation on the installation and use of X-ray equipment for medical diagnostic purposes, approved by Royal Decree 1085/2009 of 3 July 2009, are amended and shall be worded as follows:

> "4. When the medical diagnostic X-ray facility has been registered, the competent body of the Autonomous Community shall notify the licensee who submitted the declaration in writing within one month.
>
> 5. The licensee of the medical diagnostic X-ray facility may not put it into service until the competent body of the Autonomous Community notifies him or her of its entry in the register referred to in Article 15."

Second final Provision. *Enabling provisions.*

The attached regulation is issued under the provisions of Article 149.1.16 of the Spanish Constitution, which grants the State exclusive competence in matters of the bases and general coordination of health.

In addition, Title III, with the exception of Articles 8 and 15; Title IV; Articles 2, 69, 71, 72, 73, 75, 76 and 81, and the first and seventh additional provisions, are enacted under Article 149.1.7 of the Spanish Constitution, which grants the State exclusive competence in matters of labour legislation. Title V, Chapters I, II and IV of Title VII, and Articles 2, 7 and 68, are enacted under Article 149.1.23 of the Spanish Constitution, which gives the State exclusive competence over basic legislation on environmental protection. Title VI, Chapter II of Title VII, and Articles 2, 8, 25, 26, 27 and 28 are enacted under Article 149.1.29 of the Spanish Constitution, which grants the State exclusive competence in matters of public security. Articles 2 and 8 are dictated under Article 149.1.10 of the Spanish Constitution, which grants the State exclusive competence in foreign trade matters. Article 81 is also enacted under Article 149.1.20 of the Spanish Constitution, which grants the State exclusive competence in matters of airspace control, air traffic and air transport.

Third final Provision. *Incorporation of European Union Law.*

This Royal Decree transposes Articles 7, 8, 9, 10, 11, 12, 13, 20, 21, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 45, 46, 47, 48, 49, 50, 51 into Spanish law,
52, 53, 54, 66, 68, 72, 73, 75, 76, 80, 81 and 82; and Annexes I, II, IV, VIII, XIII, XVII and XVIII;
and, in part, Articles 4, 5, 6, 14, 15, 17, 18, 19, 22, 23, 28, 29, 43, 44, 65, 67, 69, 74, 77, 79, 96, 97, 98, 100, 101, 102, 103, 104 and 105, and Annex X; of the Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising

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from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

Fourth final Provision. *Regulatory empowerment.*

1. The heads of the Ministries for Ecological Transition and the Demographic Challenge; the Interior; Health; Labour and Social Economy; and Transport, Mobility and the Urban Agenda, within the scope of their competencies, may issue the appropriate provisions for the development and application of the attached regulation.

2. The annexes of the attached regulation may be updated by order of the Minister for Ecological Transition and the Demographic Challenge due to the necessary adaptation to the provisions of European Union regulations or when technical or scientific advances so advise.

3. The Nuclear Safety Council, within the scope of its competences, may issue instructions, circulars and technical guides or standards to facilitate the application of the attached regulation.

Fifth final provision. *Entry into force.*

1. The present Spanish Royal Decree shall enter into force on the day following its publication in the “Official State Bulletin”.

2. Without prejudice to the provisions of the previous paragraph, the following provisions of the attached regulation shall not apply until eighteen months after the entry into force of this Royal Decree:

a) The requirements set out in Article 19.3 for licensees of the workplaces activities set out in Article 75.1.a) and 75.1.b).

b) The requirements established in Section 1 of Chapter III of Title VII for licensees of the workplaces activities established in Article 75.1.c).

c) The obligations set out in Article 80.1 for suppliers of building materials listed in Annex VI.

Granted in Madrid, on 20 December 2022.

FELIPE R.

The Minister of the Presidency, Relations with Parliament and Democratic Memory,
FÉLIX BOLAÑOS GARCÍA

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REGULATION ON HEALTH PROTECTION AGAINST DANGERS ARISING FROM EXPOSURE TO IONISING RADIATION

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TITLE I

General provisions

CHAPTER I

Purpose and scope

Article 1. *Objective.*

1. The purpose of this Regulation is to establish rules for the protection of the health of workers and members of the public against the dangers arising from exposure to ionising radiation.

2. All exposures to ionising radiation are in one of the following three situations:

a) Planned exposure situations are those arising from the planned use of a radiation source or from a human activity that alters exposure pathways, causing exposure or potential exposure of people or the environment. Planned exposure situations may include both normal and potential exposures.

b) Emergency exposure situations are those due to a nuclear or radiological emergency.

c) Existing exposure situations are exposure situations which already exist when a decision on their control has to be taken, and which either do not or no longer require urgent action, or exposure situations created by a radiation source whose ubiquity or magnitude makes its control unjustified according to the same criteria as for a planned exposure situation. They include situations of prolonged exposure following a nuclear or radiological emergency.

Article 2. *Scope of application.*

1. This Regulation shall apply to any situation involving a risk of exposure to ionising radiation which cannot be disregarded from the point of view of radiation protection, in order to protect human health and the environment in the long term.

In particular, this Regulation shall apply to:

a) All planned exposure situations involving exposure to ionising radiation:

1.º The exploitation of radioactive minerals, the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import, export and intra-Community movement of radioactive materials of artificial or natural origin, when the radionuclides are or have been processed for their radioactive, fissionable or fertile properties.

2.º The manufacture and operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference greater than 5 kilovolts (kV).

3.º The processing, use or management of naturally occurring radioactive materials not covered in section 1.

4.º The marketing of radioactive sources and technical assistance for equipment incorporating radioactive sources or producing ionising radiation.

5.º Practices involving exposure for non-medical imaging.

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6.º Any other practice that the Directorate General for Energy Policy and Mines deems appropriate to authorise, in accordance with the provisions of Article 7.1.

b) Any intervention in emergency exposure situations, including planning and preparation.

c) All existing exposure situations:

1.º Exposure to residual contamination that may have occurred as a result of a nuclear or radiological emergency or past human activity.

2.º Exposure of crew members of aircraft and spacecraft.

3.º Exposure of workers or members of the public to radon in enclosed areas.

4.º External exposure in enclosed areas to gamma radiation from building materials.

2. This Regulation shall not apply to:

a) Radionuclides naturally contained in the human body, cosmic rays at ground level, and exposure at the earth's surface due to radionuclides present in the undisturbed earth's crust.

b) Exposure of members of the public, or workers other than aircraft or spacecraft crew, to cosmic radiation during flight or in space.

c) Medical exposures, which will be governed by the provisions of Royal Decree 601/2019, of 18 October, on the justification and optimisation of the use of ionising radiation for the radiological protection of persons on the occasion of medical exposures.

Article 3. *Regulations applicable to authorisations.*

The practices to which these regulations refer shall also comply, as regards their application and, specifically, as regards administrative authorisations, with Law 39/2015, of 1 October, on the Common Administrative Procedure of the Public Administrations; Law 25/1964, of 29 April, on nuclear energy; Law 15/1980, of 22 April, creating the Nuclear Safety Council; the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December; and the Regulation on the installation and use of X-ray equipment for medical diagnostic purposes, approved by Royal Decree 1085/2009, of 3 July 2009.

CHAPTER II

Definitions

Article 4. *Definitions.*

For the purposes of this regulation, the following definitions shall apply:

1. Activation: process by which a stable nuclide is transformed into a radionuclide when the material in which it is contained is irradiated with high-energy photons or particles.

2. Activity (A): a physical quantity that measures the rate of decay of a radionuclide corresponding to a quantity of that radionuclide in a given energy state at a given time. It is the quotient of dN and dt, where dN is the

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expected value of the number of spontaneous nuclear transitions occurring from that energy state in the time interval dt:3

$$A = dN/dt$$

The unit of activity is the becquerel (Bq). One becquerel is equal to one nuclear disintegration per second:

$$1Bq = 1\ s^{-1}$$

3. Adult: a person over 18 years of age.
4. Official year: a period of twelve months from 1 January to 31 December inclusive.
5. Competent authorities: official bodies which, in the exercise of the functions attributed to them, are responsible for granting authorisations, issuing provisions or resolutions and enforcing compliance with them, for the purposes of these regulations.
6. Authorisation: permission granted by the competent authority in documentary form to carry out a practice or any other action within the scope of this regulation.
7. Calibration: a set of operations that, under specified conditions, establishes, in a first step, a relationship between the values and their associated measurement uncertainties obtained from the measurement standards, and the corresponding indications with their associated uncertainties, and, in a second step, uses this information to establish a relationship to obtain a measurement result from an indication.
8. Radiological passport (individual radiological monitoring document): instrument for recording data, where the appropriate aspects relating to the worker are recorded, arising from the application of the radiological protection system.
9. Radioactive contamination means the accidental or undesirable presence of radioactive substances on surfaces or solids, liquids or gases, or in the human body.
10. Quality control: set of operations (programming, coordination, implementation) intended to maintain or to improve quality. It includes the monitoring, evaluation and maintenance, at the required levels, of all equipment performance characteristics that can be defined, measured and controlled.
11. Regulatory control means any form of control or regulation applied to human activities for the enforcement of radiation protection requirements.
12. Undisturbed crust: any part of the earth's crust in which no energy exploitation or mining activities are carried out, whether in quarries, underground mines or opencast mines (the surface of a deposit that has never been exploited shall be considered as undisturbed crust). Tilling, digging or levelling operations resulting from agricultural or construction activities shall be deemed not to disturb the earth's crust, except where such operations are part of the restoration of contaminated land.
13. Carers and comforters: individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;

14. Declaration: submission of information to the Ministry for Ecological Transition and the Demographic Challenge, to the competent body of the autonomous community, or to the Nuclear Safety Council to communicate the intention to carry out a practice or any other action within the scope of application of this regulation.

15.- Health detriment: reduction in length or quality of life in a population following exposure, including those arising from tissue reactions, cancer and severe genetic disorder.

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15. Individual detriment: clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance.

16. Absorbed dose (D): the energy absorbed per unit mass.

$$D = d\varepsilon/dm$$

Where dε is the mean energy imparted by ionising radiation to the matter in a volume element and dm is the mass of matter in this volume element.

In this regulation the absorbed dose denotes the dose averaged over a tissue or an organ.

The unit of absorbed dose is the grey (Gy), where one grey is equal to one joule per kilogram: 1 Gy= 1J kg^{-1}.

17. Effective dose (E): the sum of the weighted equivalent doses to all tissues and organs of the body specified in Annex I from internal and external exposures. It is estimated by the expression:

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

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

The appropriate values for w_T and w_R are specified in Annex I.

The unit for effective dose is the sievert (Sv).

Where the term "dose" is mentioned throughout this regulation, without further precision, it shall be understood to refer to "effective dose".

18. Committed effective dose [E(τ)] means the sum of the committed equivalent doses to a tissue or organ $H_T(\tau)$ as a result of an intake, each multiplied by the corresponding tissue weighting factor w_T. It is defined by the formula:

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

When specifying E(τ), τ is given in years. Where the value of τ is not specified, a period of fifty years for adults or up to the age of seventy years for children is implied.

The unit for the committed effective dose is the sievert.

19. Equivalent dose (H_T): the absorbed dose, in tissues or organs T, weighted according to the type and quality of radiation R. It is given by the formula:

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

With $D_{T,R}$ the absorbed dose averaged over the tissue or organ T, from radiation R, and w_R is the radiation weighting factor.

When the radiation field consists of types and energies with values different from w_R, the total equivalent dose is given by the formula:

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

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Appropriate values for w_R are specified in Annex I. The unit for the equivalent dose is the sievert.

20. Committed equivalent dose [$H_T(\tau)$]: Integral with respect to time (t) of the equivalent dose rate in a tissue or organ T that an individual will receive as a result of an intake. It is defined by the following formula:

$$H_T(\tau) = \int_{t0}^{t0+\tau} \dot{H}_T(t)dt$$

For an intake at time t_0, where $\dot{H}_T(t)$ s the corresponding equivalent dose rate in organ or tissue T at time t and τ is the period during which the integration takes place.

When specifying $H_T(\tau)$, τ is given in years. When the value of τ is not specified, it is means a period of fifty years for adults or up to the age of seventy years for children.

The unit for the committed equivalent dose is the sievert.

21. Radioactive effluents: residual radioactive products in liquid or gaseous form.

22. Disposal: the placement of waste at a specific site when there is no intention to recover the waste. Disposal also includes the direct discharge of waste into the environment, subject to prior authorisation, and its subsequent dispersal.

23. Nuclear or radiological emergency: an unusual situation or event involving a radiation source that requires immediate intervention 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 adverse consequences.

24. External undertaking: any natural or legal person, other than the licensee of the facility, who is to carry out activities of any kind in a supervised or controlled area of the facilities and/or activities included in the scope of application of these regulations.

25. Exposure: the act of exposing or condition of being exposed to ionising radiation emitted

26. Accidental exposure: exposure of people as a result of an accident, even if it does not result in some of the established dose limits being exceeded. It does not include emergency exposure.

27. Radon exposure: exposure to the radionuclide Rn-222 and its short half-life progeny.

28. Emergency exposure: voluntary exposure of people taking urgent action to provide assistance to people in danger, preventing the exposure of large numbers of people or saving valuable facilities or property, which may involve going over any of the limits of individual doses established for exposed workers.

29. Exposure of members of the public: exposure of individuals, excluding any occupational or medical exposure.

30. External exposure: the act of exposing or condition of being exposed to ionising radiation emitted outside the body.

31. Internal exposure: the act of exposing or condition of being exposed to ionising radiation emitted within the body

32. Medical exposure: exposure to patients or asymptomatic persons as part of their own medical or dental diagnosis or treatment, intended to benefit their health or well-being, as well as exposure incurred to carers and comforters and volunteers in medical or biomedical research.

33. Normal exposure: exposure expected under normal conditions of operation of a facility or activity (including maintenance, inspection and decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences

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34. Occupational exposure: exposure of workers, apprentices and students incurred in the course of their work.

35. Non-medical imaging exposure: 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

36. Potential exposure: 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

37. Extremities: hands, forearms, feet and ankles.

38. Natural background radiation: ionising radiation coming from internal, l terrestrial or cosmic sources.

39. Radiation source: an entity that can cause exposure, such as by emitting ionising radiation or by releasing radioactive material.

40. Natural radiation sources: sources of ionising radiation of natural, terrestrial or cosmic origin.

41. Radioactive source: a source of radiation containing radioactive material for the purpose of utilising its radioactivity.

42. Quality assurance: all planned and systematic actions that are necessary to provide sufficient assurance that a structure, system, component or procedure will perform satisfactorily in accordance with approved standards. Quality control is part of quality assurance.

43. Incorporation: total activity of radionuclides entering the organism from the external environment.

44. Registration: permission granted by the competent authority in documentary form, by means of a simplified procedure, upon request, to carry out a practice, in accordance with the conditions laid down in the nuclear energy regulations.

45. Inspection: investigation carried out by any competent authority to verify compliance with legal requirements.

46. Intervention: human activity that prevents or reduces the exposure of people to radiation from sources that are not part of a practice or that are out of control, acting on sources, transfer channels or the people.

47. Head of Radiation Protection Service or Technical Unit: person responsible for or in charge of a Radiation Protection Service or Technical Unit accredited for this purpose by means of a diploma issued by the Nuclear Safety Council.

48. Licence: personal and non-transferable permit granted to a physical person by the Nuclear Safety Council, in documentary form, authorising him/her to operate or supervise the operation of a nuclear or radioactive facility.

49. Dose limit: the value of the effective dose (where appropriate, the committed effective dose), or the equivalent dose, in a specified period, which shall not be exceeded for an individual.

50. Building material: any construction product which is intended to be permanently incorporated into 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 ionizing radiation

51. Radioactive material: material containing radioactive substances.

52. NORM material (acronym for Naturally Occurring Radioactive Material): material containing radionuclides of natural origin in concentrations in excess of the exemption levels laid down in the regulations in force, excluding material which is processed, used or exploited because of its fissile or radioactive properties.

53. Remedial action means actions aimed at the elimination of a radioactive source or the reduction of its magnitude (in terms of activity or quantity) or the interruption of exposure pathways or the reduction of its impact, with the aim of

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avoidance or reduction of doses that might otherwise be received in an existing exposure situation.

54. Protective measures: measures, other than remedial measures, intended to prevent or reduce doses that might otherwise be received in an emergency exposure situation or in an existing exposure situation.

55. Members of the public: persons who may be subject to non-occupational or non-medical exposure.

56. Child: a person under 18 years of age.

57. Reference level: level of effective dose, equivalent dose, or activity per unit mass or volume in an emergency or existing exposure situation, above which it is considered inappropriate to allow exposures to occur, even though it is not a limit that cannot be exceeded, but a tool for the optimisation of radiation protection.

58. Representative person: individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;

59. Apprentice or student: a person who, not being a worker, receives training or instruction in a company in order to perform a specific function.

60. Emergency workers: any person who has a defined role in a nuclear or radiological emergency and who may be exposed to radiation while acting in response to the emergency.

61. Population: a group of people comprising exposed workers, students and apprentices, members of the public and patients of diagnostic, interventional and therapeutic procedures.

62. Practice: a human activity which may increase the exposure of people to radiation from a radiation source and which is managed as a planned exposure situation.

63. Processing: chemical or physical handling with radioactive material, including extraction of mineral, conversion, enrichment of fissile or fertile nuclear material and reprocessing of spent fuel.

64. Consumer product: a device or manufactured item in which one or more radionuclides have deliberately been incorporated or produced by activation, or which generates ionising radiation, and which may be sold or made available to members of the public, without special surveillance or regulatory control after sale.

65. Promoter: a physical or legal person who for the first time in the country intends to carry out a new practice.

66. Radiation protection: the set of standards and procedures used to prevent the risks of receiving radiation doses and, where appropriate, to mitigate and remedy their effects.

67. Ionising radiation: transfer of energy in the form of particles or electromagnetic waves of a wavelength equal to or less than 100 nanometres or a frequency equal to or greater than 3×10^{15} hertz, capable of directly or indirectly producing ions.

68. Radon: the radionuclide Rn-222 and its short half-life progeny, as appropriate.

69. Enclosure means any space enclosed by architectural features or artificial or natural structures that separate it from the outside environment or other interior spaces, and to which people have access.

70. Radioactive waste: any waste material or product for which no use is intended that contains or is contaminated with radionuclides at concentrations or levels of activity higher than those established by the Ministry of Industry and Energy following a report from the Nuclear Safety Council.

71. NORM waste: waste material or product, excluding those arising from activities in which there has been a processing, use or disposal of waste material or product, and excluding those arising from activities in which there has been a processing, use or disposal of waste material or product

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use of a material on account of its fissile or radioactive properties, for which no use is foreseen by the licensee of the activity in which it was generated, and which contains or is contaminated with radionuclides of natural origin in concentrations or activity levels higher than those established in the regulations in force.

72. Dose constraint: a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the optimisation process for a given radiation source in planned exposure situations.

73. Personal Dosimetry Service: entity responsible for the calibration, reading or interpretation of monitoring systems, or for the measurement of radioactivity in the human body or in biological samples, or for dose assessment, whose capability to act in this respect is recognised by the Nuclear Safety Council.

74. Prevention Service: all the human and material resources necessary to carry out preventive activities in order to guarantee the adequate protection of the health and safety of workers, advising and assisting the employer, the workers and their representatives and the specialised representative bodies.

75. Radiation Protection Service and Technical Unit: entity expressly authorised by the Nuclear Safety Council to perform the functions established in these regulations. The Radiation Protection Service is an entity owned by a licensee or jointly owned by several licensees, while the Radiation Protection Technical Unit is an external entity contracted by the licensee.

76. Sievert (Sv): special name for the unit of effective and equivalent dose. One sievert is equal to one joule per kilogram:

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

77. Emergency management system: the legal or administrative framework which, under national legislation, establishes responsibilities for nuclear or radiological emergency preparedness and response, as well as arrangements for decision-making in the event of an emergency exposure situation.

78. Supervisor: a person holding a specific licence granted by the Nuclear Safety Council, who is qualified to direct the operation of a nuclear or radioactive facility and the activities of handling the facility's control and protection devices. All this in accordance with the provisions of the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December.

79. Radioactive substance: a substance that contains one or more radionuclides and whose activity or concentration of activity cannot be disregarded from the point of view of radiation protection.

80. Radiation protection technician: a duly qualified person who forms part of a Radiation Protection Service or Technical Unit and who, under the direction of the Head of the Radiation Protection Service or Technical Unit, carries out the activities of said Service or Unit.

81. Licensee (or company) means the physical or legal person who has, under national legislation, responsibility for a radiation source (including cases where the owner or holder of the radiation source has no activities related to it) or for the exercise of any of the work practices or activities referred to in Article 2.

82. Thoron: the radionuclide Rn-220 and its short half-life progeny, as appropriate.

83. Exposed worker: a person who, whether employed or self-employed, is subject to exposure at work in a practice covered by these regulations, who is liable to receive doses exceeding any of the dose limits for members of the public or who, involving exposure to radon or cosmic radiation in aircraft or spacecraft, is engaged in work activities which are managed as planned exposure situations.

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84. Outside worker: any exposed worker who is employed on a temporary or permanent basis by an external company, carrying out an activity of any nature in a supervised or controlled area of the facilities or activities included in the scope of application of these regulations. This includes apprentices or students and self-employed persons engaged in such activities.

85. Space vehicle: manned vehicle designed to operate at an altitude of more than 100 km above sea level.

86. Environmental monitoring: measurement of external dose rates due to the presence of radioactive substances in the environment or the measurement of radionuclide concentrations in the natural environment.

87. Controlled area: an area which is subject to special regulation for the purpose of protection against ionising radiation, or to prevent the spread of radioactive contamination, and to which access is controlled.

88. Supervised area: an area under surveillance for the purpose of protection against ionising radiation.

CHAPTER III

Responsibility

Article 5. *Liability.*

The application of the principles set out in this Regulation is the responsibility of the licensee of the practice or activity giving rise to an exposure situation within the scope of his activity and competence.

TITLE II

Radiation protection system

SINGLE CHAPTER

General principles

Article 6. *General principles.*

The control of all situations of exposure to ionising radiation is founded on a radiation protection system based on the following principles:

a) Justification: Decisions to introduce a practice shall be justified by an analysis that ensures that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified by demonstrating that the new situation is more beneficial than harmful.

b) Optimisation: the radiation protection of persons subject to occupational exposure or as members of the public shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and social factors. This principle shall apply not only to the effective dose but also, where appropriate, to equivalent doses, as a precautionary measure to allow for uncertainties regarding the existence of health detriment below the threshold for tissue reactions

c) Dose limitation: in planned exposure situations, the sum of the doses received by any individual shall not exceed the dose limits established for both occupational exposure and exposure of members of the public. The dose

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limits apply to the sum of doses from external exposures in the specified period and doses committed at fifty years (up to seventy years in the case of children) from intakes occurring in the same period. Doses due to natural background radiation shall not be included in the calculation, except in the activities referred to in Article 75, nor shall doses arising from medical examinations and treatment.

Without prejudice to the foregoing, this principle shall not apply to the deliberate and voluntary exposure of persons, where this is not part of their occupation, to support or comfort patients undergoing medical diagnosis or treatment; nor to the exposure of volunteers participating in medical and biomedical research programmes.

TITLE III

Planned exposure situations

CHAPTER I

Justification

Article 7. *Justification of practices.*

1. Any new class or type of practice included in the scope of application of this regulation must be justified by its promoter to the Directorate General for Energy Policy and Mines, providing the latter with the information that accredits such justification.

The said Directorate General, following a report from the Nuclear Safety Council, shall decide whether authorisation is appropriate.

2. When there is new and important evidence about the efficacy or potential consequences of any class or type of practice or relevant information is obtained on other techniques and technologies, the Directorate General for Energy Policy and Mines shall consider the possibility of reviewing the justification for this class or type of practice and, if necessary, request from its promoter a justification of the practice in accordance with the new situation, deciding, following a report from the Nuclear Safety Council, whether the continuation of this practice is appropriate.

The promoter of the practice shall provide information to the Directorate General for Energy Policy and Mines on any new and important evidence about the efficacy or potential consequences of any kind or type of practice, as well as on other techniques and technologies justified by him or her.

In these cases of significant new evidence regarding the efficacy or potential consequences of any class or type of practice, the review of the justification shall also be carried out if there is a proposal from the Nuclear Safety Council to the Directorate General for Energy Policy and Mines.

3. For the justification of practices related to consumer products, all relevant information, including that listed in paragraph 1 of Annex II, shall be provided to the Directorate General for Energy Policy and Mines, and the Directorate General for Energy Policy and Mines will assess this information, as set out in Annex II paragraph 2.

The Directorate General for Energy Policy and Mines shall inform the contact point of the competent authorities of the other Member States of its receipt and, upon request, of its decision and the basis for that decision.

4. The provisions of paragraphs 1 and 2 shall apply to all exposures to ionising radiation resulting from the practices referred to in Article 2.1.a).

5. Practices involving multiple exposure (occupational and members of the public) shall be justified as a class or type of practice, taking into account all categories of exposure.

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Article 8. *Prohibitions and special requirements.*

1. The deliberate administration of radioactive substances to humans and, in so far as the radiation protection of humans is concerned, to animals, for the purpose of diagnosis, treatment or research of a medical or veterinary nature, shall only be carried out in radioactive facilities authorised for that purpose.

2. The sale or the making available to the public of consumer products if their intended use is not justified in accordance with Article 7 shall be prohibited.

Without prejudice to the provisions of Royal Decree 348/2001, of 4 April, which regulates the preparation, marketing and importation of foodstuffs and food ingredients treated with ionising radiation, practices involving the activation of material resulting in an increase in activity in a consumer product, which at the time of placing on the market cannot be disregarded from the point of view of radiological protection, shall be deemed not to be justified. However, the Directorate General for Energy Policy and Mines may assess specific types of practices within this class with regard to their justification

3. The addition of radioactive substances in the production of foodstuffs, animal feeding stuffs, toys, personal ornaments and cosmetics, as well as the import, export or intra-Community movement of such goods when they incorporate radioactive substances shall be prohibited.

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

5. The deliberate exposure of persons for non-medical imaging purposes shall be prohibited, except where such practices have been expressly justified and authorised.

All practices involving non-medical imaging procedures shall be authorised by the Directorate General for Energy Policy and Mines in accordance with Article 7.1

Those procedures in which medical diagnostic equipment is used shall be carried out in health centres or establishments authorised and registered for this activity in application of Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of health centres, services and establishments.

6. In general, any practice that is not considered justified shall be prohibited, regardless of whether the levels of radiation or activity handled were below those established for exemption from authorisation, declaration or application for registration.

CHAPTER II

Optimisation

Article 9. *Dose constraints.*

1. In compliance with the principle of optimisation of radiation protection, where appropriate, dose constraints, in terms of individual effective dose or equivalent dose per official year, may be established and shall be supervised by the Nuclear Safety Council.

2. For occupational exposures, the practice licensee shall establish these constraints as an optimisation tool under the general supervision of the Nuclear Safety Council. In the case of outside workers, the dose r constraints shall be established by the licensee of the facility in coordination with the employer of the outside workers.

3. For exposure of members of the public, the Directorate General for Energy Policy and Mines, following a report from the Nuclear Safety Council, shall establish the

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individual dose constraint that a person may receive from the planned use of a specific radiation source. The Nuclear Safety Council shall ensure that constraints are consistent with the dose limit for the sum of doses to the same person from all authorised practices.

4. The licensee of the practice shall establish dose constraints, on the basis of guidance to be provided by the Nuclear Safety Council, in the procedures to be applied to exposed persons in accordance with the principles defined in Article 6.

CHAPTER III

Dose limitation

Article 10. *Usage.*

1. For exposed workers, the corresponding dose limits laid down in Article 11 shall apply to the sum of the annual occupational exposures from all authorised practices, from occupational exposure to radon in the workplace where the concentration of radon in any area of the workplace exceeds the reference level laid down in Article 72, and from other occupational exposures resulting from existing exposure situations in accordance with Title VII, without prejudice to Article 14.

2. For members of the public, the sum of the doses received from all practices shall not exceed the relevant dose limit laid down in Article 15, with the exception of non-medical imaging exposures.

Article 11. *Dose limits for exposed workers.*

1. The limit on the effective dose for exposed workers shall be 20 mSv per official year.

2. Without prejudice to paragraph 1, the following limits shall apply:

a) The limit on the equivalent dose for the eye lens shall be 100 mSv over five consecutive official years, subject to a maximum dose of 50 mSv in a single official year.
b) The limit on the equivalent dose for skin shall be 500 mSv per official year. This limit shall apply to the dose averaged over any skin area of 1 cm_2 regardless of the area exposed.
c) The limit on the equivalent dose for the extremities shall be 500 mSv per official year.

Article 12. *Dose limit during pregnancy and activities during lactation.*

1. As soon as a worker notifies her pregnancy status to the licensee of the practice, or to the outside company in the case of outside workers, the protection of the unborn child shall be comparable to that provided for members of the public. Therefore, the working conditions of the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and not exceeding 1 mSv, at least from the time of notification of her condition until the end of pregnancy.

2. As soon as a worker who is breastfeeding notifies the licensee of the practice, or the outside company in the case of outside workers, of her condition, she shall not be employed in work involving a significant risk of intake of radionuclides or radioactive contamination.

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Article 13. *Dose limit for apprentices and students:*

1. The dose limits for trainees and students aged over eighteen years who are required to use radiation sources in the course of their studies shall be the same as those for occupational exposure set out in Article 11.

2. The effective dose limit for apprentices and students aged between sixteen and eighteen years who are required to use radiation sources during their studies shall be 6 mSv per official year.

Without prejudice to this dose limit:

a) The limit on the equivalent dose for the eye lens shall be 15 mSv per official year.

b) The limit on the equivalent dose for skin shall be 150 mSv per official year. This limit shall apply to the dose averaged over any skin area of 1 cm_2 regardless of the area exposed.

c) The limit on the equivalent dose for the extremities shall be 150 mSv per official year.

3. The dose limits for trainees and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as those laid down in Article 15 for members of the public.

Article 14. *Specially authorised exposures*

1. In exceptional situations, excluding accidental exposures and emergency exposure situations, the Nuclear Safety Council may authorise, on a case-by-case basis, individual occupational exposures in excess of the effective dose limit laid down in Article 11.

2. The authorisation referred to in the previous paragraph shall only be granted when the exposures are limited in time, confined to certain working areas and within the maximum dose levels per exposure defined for that particular case by the Nuclear Safety Council. The following conditions shall be taken into account:

a) Only category A exposed workers as defined in Article 22 or spacecraft crews shall be subject to specially authorised exposures.

b) The participation in specially authorised exposures shall not be authorised to

1.º Pregnant workers and, if there is a risk of intake of radionuclides or bodily contamination, workers who are breastfeeding.

2.ºApprentices or students.

c) The licensee of the practice shall justify such exposures in advance and inform with reasons the workers involved, their representatives, the Prevention Service that carries out the medical surveillance and control of the workers, the Radiation Protection Service or the Technical Radiation Protection Unit or, failing this, the Supervisor or the person entrusted with the radiation protection functions.

d) Before participating in a specially authorised exposure, workers shall be given adequate information about the risks involved and the precautions to be taken during the operation. The participation of such workers shall be of a voluntary nature.

3. Exceeding dose limits as a result of specially authorised exposures shall not constitute a reason for excluding the worker from their usual occupations or relocating them without their agreement. Subsequent exposure conditions must be submitted, by the licensee of the practice, to the criteria of the Prevention Service that carries out the medical surveillance and control of the workers.

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4. Exposure of spacecraft crews above the dose limits shall be managed as specially authorised exposure in accordance with paragraphs 1, 2 and 3.

Article 15. *Dose limits for members of the public.*

1. The effective dose limit for members of the public shall be 1 mSv per official year.
2. Without prejudice to paragraph 1:

a) The limit on the equivalent dose for the eye lens shall be 15 mSv per official year.
b) The limit on the equivalent dose for skin shall be 50 mSv per official year. This limit shall apply to the dose averaged over any skin area of 1 cm_2 regardless of the area exposed.

CHAPTER IV

Estimation of effective and equivalent doses

Article 16. *Dose estimation criteria.*

1. For the estimation of effective and equivalent doses, the values, relationships and guidelines referred to in this Title shall be used, as follows:

a) For external radiation, Annex I shall be applied to estimate the relevant effective and equivalent doses.
b) For internal exposure from a radionuclide or a mixture of radionuclides, Annexes I and III shall be applied to estimate the committed effective doses.

The Nuclear Safety Council may authorise the use of equivalent methods in appropriate cases.
2. The provisions of this Article shall apply to all exposure situations within the scope of this Regulation.

TITLE IV

Fundamental principles of occupational protection of exposed workers, apprentices and students

CHAPTER I

Occupational protection of exposed workers

Article 17. *Principles of occupational protection of exposed workers.*

Occupational protection of exposed workers shall be based on the following principles:

a) Prior assessment of working conditions to determine the nature and magnitude of the radiological risk and to ensure that the principle of optimisation is applied.
b) Classification of workplaces into different areas, taking into account: the assessment of expected annual doses, the risk of dispersion of contamination and the likelihood and magnitude of potential exposures.
c) Classification of exposed workers into different categories according to their working conditions.

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d) Application of surveillance and control rules and measures relating to the different areas and to the different categories of workers exposed, including, where appropriate, individual surveillance.
e) Medical monitoring.
f) Information and training.

CHAPTER II

Prevention of exposure

Section 1.1 Classification and delimitation of areas

Article 18. *Assessment and classification of areas.*

1. The licensee shall, following a preliminary assessment, classify workplaces, on the basis of the risk of exposure and taking into account the likelihood and magnitude of potential exposures, into the following areas:

a) Controlled area. An area in which any of the following conditions are met:

1.º There is a possibility of receiving effective doses in excess of 6 mSv per official year.
2.º It is necessary to follow work procedures in order to restrict exposure to ionising radiation, to avoid significant dispersion of radioactive contamination or to prevent or limit the likelihood and magnitude of radiological accidents or their consequences.

b) Supervised area: An area which, not being a controlled area, has the potential to receive effective doses in excess of 1 mSv per official year.

2. In addition, the controlled areas may be subdivided into the following:

a) Limited-stay area: Those where there is a risk of receiving a dose in excess of the dose limits laid down in Article 11.
b) Regulated stay areas: These are areas where there is a risk of receiving, in short periods of time, a dose in excess of the dose limits laid down in Article 11 and which require special prescriptions from the point of view of optimisation.
c) Prohibited-access area: Those areas where there is a risk of receiving, in a very short period of exposure, doses in excess of the dose limits laid down in Article 11.

3. The classification of workplaces in the established areas shall be updated according to the actual existing conditions, and the licensee of the practice shall review the classification of areas on the basis of radiological variations in these areas.

Article 19. *Workplace measures.*

1. For radiation protection purposes and following a prior assessment to determine the nature and magnitude of the radiological risk to exposed workers, the licensee shall identify, delimit and classify all workplaces where there is a possibility of receiving effective doses in excess of 1 mSv per official year and shall establish the applicable radiation protection measures. Such measures shall be adapted to the nature of the facilities and sources, and to the working conditions and rules, as well as to the magnitude and nature of the risks. The extent of the means of prevention and surveillance, their nature and quality must be appropriate to the risks associated with the work involving

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exposure to ionising radiation. The risk of exposure to ionising radiation and the radiological protection measures must be considered, in an integrated manner, in the occupational risk prevention plans, in the risk assessments and in the preventive activity planning required by Law 31/1995, of 8 November, on the prevention of occupational risks.

2. Where there are areas in a workplace where the concentration of radon in air exceeds the reference level set out in Article 72(a), despite measures taken in accordance with the principle of optimisation, the licensee of the practice:

a) Reassess airborne radon concentrations at a frequency to be established in each case by the Nuclear Safety Council.

b) It shall estimate the annual effective doses due to radon that may be received by workers with access to such areas, and these doses shall not be counted for compliance with Articles 18 and 22.

c) It shall classify as radon-exposed workers those workers who are likely to receive an effective dose from exposure to radon in excess of 6 mSv per official year.

d) Classify and sign radon areas as those areas where there is a concentration of radon in air which may result in an effective dose to workers in excess of 6 mSv per official year.

3. Where any of the workplaces referred to in Article 75.1 have workers whose annual effective dose due to radon may exceed 6 mSv, the licensee of the work activity shall establish the applicable radiation protection measures. The scope of these shall depend on the associated risk and, in particular, Articles 11, 16, 19.2 c) 19.2.d), 23, 24, 25, 31.2, 31.3, 31.4, 32, 36 , 39.1, 40.2, 42 and 43 shall apply.

4. In operating aircraft where the annual effective dose to the crew due to exposure to cosmic radiation is liable to exceed 6 mSv per official year, the licensee shall manage this exposure in accordance with this Regulation.

Article 20. *Area requirements.*

1. In supervised areas, at least an estimation of the doses likely to be received shall be made by area dosimetry.

2. Taking into account the nature and significance of the radiological risks, the licensee shall carry out radiological monitoring of workplaces in controlled and surveyed areas in accordance with Article 31. In addition, these areas:

a) Shall be adequately limited and signposted in such a way as to indicate the risk of exposure. This signposting shall be carried out in accordance with Annex IV.

b) Access shall be limited to authorised persons who have received training and instructions appropriate to the risk within such areas. In controlled areas these instructions shall be in accordance with the working procedures established in writing by the licensee.

3. In controlled areas where it exists:

a) External exposure risk: an individual dose estimation shall be mandatory, which, in the case of category A exposed workers, shall be based on individual dosimetry, except when the Nuclear Safety Council expressly accepts alternatives proposed by the licensee based on the special characteristics of the workplace.

b) Internal contamination risk, the use of personal protective equipment appropriate to the risk involved is mandatory. At the exit of these areas, there shall be suitable

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detectors to check for possible contamination of persons and equipment and, if necessary, to take appropriate measures.

4. The licensee of the practice shall be responsible for ensuring that the provisions of paragraphs 1, 2 and 3 are complied with, and that this is carried out with the advice and supervision of the Radiation Protection Service or the Radiation Protection Technical Unit or, failing this, of the Supervisor or person entrusted with radiation protection duties.

Section 2. Classification of exposed workers

Article 21. *Age limit for exposed workers.*

Without prejudice to the provisions of Article 13.2. persons under the age of eighteen years shall not be assigned to tasks which are likely to make them exposed workers.

Article 22. *Categorisation of exposed workers.*

1. For reasons of radiological surveillance and control, the licensee or, where appropriate, the external company, shall be responsible for categorising exposed workers into two categories:

a) Category A: This category includes exposed workers who, because of the conditions under which their work is performed, are liable to receive an effective dose greater than 6 mSv per official year or an equivalent dose greater than 15 mSv per official year for the eye lens or greater than 150 mSv for the skin and extremities.
b) Category B: Exposed workers who are not classified as category A workers

2. The licensee of the facility or activity or, where appropriate, of the external undertaking, must decide on the classification of individual workers before they take up work that may give rise to exposure, and to regularly review this categorisation on the basis of working conditions and medical surveillance. The distinction shall also take into account potential exposures.

Section 3. Information and training

Article 23. *Information and training.*

1. The licensee or, where appropriate, the external company, shall inform its exposed workers, apprentices and students who have to use radiation sources during their studies, before starting their activity, about:

a) Health risks related to exposure to radiation in the workplace.
b) General radiation protection procedures and precautions to be taken.
c) The radiation protection procedures and precautions to be taken in relation to the operational and working conditions, both of the practice in general and of each type of work that may be assigned to them.
d) Relevant aspects of emergency response plans and procedures.
e) The importance of compliance with technical, medical and administrative requirements.
f) In the case of female workers, the need to communicate as soon as possible the situation of pregnancy and the breastfeeding period, taking into account the risks of exposure for

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the foetus, as well as the risk of contamination of the unborn child in case of intake of radionuclides or internal contamination.

1. The licensee or, where appropriate, the external company, shall provide exposed workers, apprentices and students with training in radiation protection at a level and frequency appropriate to their responsibility and the risk of exposure to ionising radiation in their workplace.

2. The licensee of the practice or activity or, where appropriate, of the external company, shall not offer benefits to the worker in exchange for relaxation of protective measures.

Section 4.1 Application of radiation protection measures

Article 24. *Application of radiation protection measures for exposed workers.*

The licensee of the practice shall be responsible for ensuring that the examination and control of protection devices, techniques and measuring instruments are carried out in accordance with established procedures, and with the advice and supervision of the Radiation Protection Service or the Radiation Protection Technical Unit or, failing this, of the Supervisor or person entrusted with the radiation protection functions, and shall include, in particular:

a) Prior critical examination of the installation or work activity projects from the point of view of radiation protection.

b) The acquisition and commissioning of new or modified radiation sources, from the point of view of radiation protection.

c) Periodic testing of the effectiveness of protective devices and techniques.

d) Calibration, verification and periodic checking of the good condition and functioning of measuring instruments.

e) Verification that detection equipment is used properly.

Article 25. *Radiological Protection Technical Services and Units*

Without prejudice to the provisions of the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December, the Nuclear Safety Council, considering the radiological risk, may require the licensees of the activities included in article 2.1.a) to provide themselves with a Radiation Protection Service (SPR) or to contract a Technical Radiation Protection Unit (UTPR) for specific advice on radiation protection and the performance of the functions in this area attributed to such licensees in accordance with this regulation.

Article 26. *Authorisation and organisation of Radiation Protection Services and Technical Units.*

1. The Radiation Protection Services and Technical Units shall be expressly authorised by the Nuclear Safety Council and shall be made up of the Head of the Radiation Protection Service or Technical Unit and the radiation protection technicians.

2. The Radiation Protection Services shall be organised and act independently from the rest of the functional units and the Head of this Service shall report directly to at least the functional head or, where appropriate, to the person with ultimate responsibility at the facility or centre. This is without prejudice to the necessary coordination with the Prevention Services established in labour legislation.

3. Radiation Protection Services and Technical Units may operate in more than one facility when authorised to do so by the Nuclear Safety Council.

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Article 27. *Accreditation and obligations of the Head of the Radiation Protection Service or Technical Unit.*

1. The Head of the Radiation Protection Service or Technical Unit shall hold a diploma issued by the Nuclear Safety Council accrediting him/her as such.

2. The Head of the Radiation Protection Service or Technical Unit shall ensure compliance with these regulations. In the event of non-compliance, the licensee shall be obliged to notify the licensee of the practice in writing, keeping the corresponding record at the disposal of the Nuclear Safety Council Inspectorate. Similarly, it shall request in writing to the licensee of the practice to stop the work or to vacate an area when it considers that the radiation protection requirements are not being met.

Article 28. *Functions of the Radiation Protection Service or Technical Unit.*

The Radiation Protection Service or Technical Unit shall be assigned the functions applicable to it, or contracted to it by the licensee, of the following:

a) Optimisation and establishment of dose constraints.
b) Planning of new facilities and authorisation of commissioning of new radiation sources. Pre-risk assessment.
c) Radiological classification of work areas.
d) Categorisation of exposed workers.
e) Dosimetric surveillance of exposed workers.
f) Dose assignment to exposed workers based on the dosimetry data provided by the authorised Personal Dosimetry Service.
g) Updating and maintenance of dosimetry records of exposed workers.
h) Radiological surveillance of workplaces.
i) Determination of characteristics of instrumentation for radiation monitoring; checks, calibrations and associated quality assurance.
j) Effluent and radioactive waste management and NORM waste.
k) Environmental radiological monitoring and public dose control.
l) Elaboration and application of working procedures for the reception control, handling, transport and storage of radioactive material.
m) Establishment of accident and incident prevention measures.
n) Preparedness and intervention in emergency exposure situations.
ñ) Training and further training programmes for exposed workers.
o) Investigation and analysis of accidents, incidents and corrective measures.
p) Risk assessment and definition of working conditions for pregnant and breastfeeding workers.
q) Preparation of the Radiation Protection Manual and associated procedures subject to quality assurance.
r) Record keeping and archiving.
s) Preparation of the necessary radiation protection documentation.

Article 29. *Radiation protection technician.*

Recognition as a radiological protection technician shall be carried out in accordance with Instruction IS-03, of the Nuclear Safety Council, on qualifications for recognition as an expert in protection against ionising radiation, or with Instruction IS-33, of the Nuclear Safety Council, on radiological criteria for protection against exposure to natural radiation, as appropriate. The requirements for obtaining such recognition shall be communicated to the European Commission.

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Article 30. *Specific provisions for the Radiation Protection Services and Technical Units of health centres or institutions.*

In compliance with the provisions of Royal Decree 183/2008, of 8 February, which determines and classifies specialities in Health Sciences and develops certain aspects of the specialised health training system, as well as Royal Decree 601/2019, of 18 October, on the justification and optimisation of the use of ionising radiation for the radiological protection of people during medical exposures, and other health regulations on the subject:

a) The Heads of Radiological Protection Services of medical centres or institutions shall hold the title of Specialist in Hospital Radiophysics and, as such, shall have the functions assigned to them in the aforementioned Royal Decrees.
b) The Radiological Protection Technical Units that provide services in medical centres or institutions must incorporate a Specialist in Hospital Radiophysics into their organisation, who will have the functions assigned to him/her in the aforementioned royal decrees.

CHAPTER III

Monitoring and exposure assessment

Section 1.1 Radiological surveillance of workplaces

Article 31. *Radiological surveillance of workplaces.*

1. The radiological surveillance of workplaces referred to in Article 20.2 shall comprise:

a) The measurement of external dose rates, specifying the nature, type and quality of the radiation concerned.
b) The measurement of activity concentrations in air and surface contamination, specifying the nature of the contaminating radioactive substances and their physical and chemical states.

2. In the workplaces specified in Article 19.3, monitoring shall include:

a) The measurement of radon activity concentration in air.
b) In cases to be determined by the Nuclear Safety Council, measurement of the equilibrium factor and aerosol size distribution, or measurement of the activity concentrations in air of short-lived radon progeny.

3. The documents corresponding to the recording, evaluation and result of such surveillance shall be kept on file by the licensee of the practice, who shall keep them at the disposal of the Prevention Service and the corresponding competent authorities.
4. Where appropriate, the results of these measurements shall be used to estimate individual doses in accordance with Articles 34 and 35.

Section 2. Individual monitoring

Article 32. *Individual monitoring*

1. The doses received by exposed workers shall be determined in accordance with Articles 33 and 34 under normal working conditions, at intervals not exceeding one month, for external dosimetry; and

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with the periodicity established in each case, for internal dosimetry, for those workers who are exposed to the risk of radionuclide intakes.

2. Individual dosimetry, both external and internal, shall be carried out on the basis of dosimetry data provided by the Personal Dosimetry Services expressly authorised by the Nuclear Safety Council. These services shall forward the results of this monitoring to the licensee of the practice or, where appropriate, to the external company.

3. The results of the individual surveillance of exposed workers shall also be sent to the Nuclear Safety Council, accompanied by the information necessary to allow the appropriate identification of these workers, the company employing them, the facilities in which they carry out their work and the type of work performed by them. The Nuclear Safety Council will include these results in the National Dosimetry Bank (BDN), which will be subject to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

4. In the event of the assignment of doses different from those provided by the Personal Dosimetry Service, the licensee of the practice shall inform the Personal Dosimetry Service of this circumstance, as well as the dose finally assigned.

5. The licensee of the practice or, where appropriate, the external company, shall transmit the results of the dosimetric controls, for the purposes of their assessment, to the Prevention Service that carries out surveillance and control of the health of the workers. In case of urgency, such transmission shall be immediate.

Article 33. *Estimation of doses for category A workers.*

For exposed workers belonging to category A, it shall be compulsory:

a) In case of risk of external exposure, the use of individual dosimeters measuring the external dose, representative of the dose to the whole body over the whole working day.

b) In case of risk of partial or non-homogeneous exposure of the organism, the use of appropriate dosimeters in the body parts potentially most affected.

c) In case of risk of internal exposure, the carrying out of appropriate measures or analyses to assess the doses involved.

Article 34. *Estimation of doses for category B workers.*

The individual doses received by exposed workers in category B may be estimated on the basis of the results of the radiological surveillance carried out in the workplaces provided for in Article 31, provided that these make it possible to demonstrate that such workers are correctly classified in category B.

Article 35. *Special dose assignment*

In cases where it is not possible to estimate the doses of exposed workers (due to loss, damage, non-replacement of the dosimeter, or other reasons), the dose assignment shall be based on an estimate made on the basis of individual measurements taken on other exposed workers who have carried out similar work, on the basis of the results of the radiological surveillance of workplaces provided for in Article 31, or on the basis of previous doses received in similar activities, this fact being expressly stated in the worker's dosimetry history.

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Article 36. *Systematics applicable to area dosimetry.*

The systematics for the use of dosimeters or instruments used for area dosimetry and the associated dose assignment procedure shall be included in a written protocol, subject to evaluation and inspection by the Nuclear Safety Council.

Article 37. *Dose assessment in accidental and emergency exposures.*

In case of accidental exposures the licensee of the practice shall assess the associated doses and their distribution in the body. In case of emergency exposures the licensee shall carry out individual monitoring or individual dose assessments, depending on the circumstances.

Article 38. *Exceeding dose limits.*

1. Where, as a result of specially authorised exposure, accidental exposure or emergency exposure, the dose limits laid down in Article 11 may have been exceeded, a survey shall be carried out in order to assess, as rapidly and accurately as possible, the doses received in the whole body or in the regions or organs concerned.
2. These cases and the results of the study shall be brought without delay, by the licensee of the practice or the external company, to the attention of the Prevention Service responsible for the surveillance and control of workers' health, the Nuclear Safety Council, the health authority and the worker concerned.

Section 3. Recording and reporting of results

Article 39. *Dosimetric history and additional records.*

1. It shall be compulsory to record all doses received by category A and B workers with individual dosimeters during their working lives in an individual dose record that shall be kept up to date and be available to the worker at any time.
For this purpose, the following documents must also be recorded, kept and made available to the employee:

a) In the case of exposures referred to in Articles 37 and 38, reports on the circumstances and measures taken.
b) The results of workplace monitoring used to estimate individual doses.

2. The individual dose record of an exposed worker in category A shall also be included in his or her medical-occupational history referred to in Article 49.

Article 40. *Content of the individual dose record.*

1. The individual dosimetry records for category A workers shall record the monthly doses and the cumulative doses per official year. For category B workers, the annual assigned or estimated doses shall be recorded.
In the case of workers who are assigned doses for the eye lens in their dosimetry history, the doses accumulated in five official years shall be additionally included.

2. For workers exposed to radon, the dosimetry history shall record the cumulative doses per official year, as well as the relevant parameters for the estimation of these doses

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Article 41. *Dose records for specially authorised exposure, accident or emergency.*

Any dose received as a consequence of a specially authorised exposure shall be recorded as such in the individual dosimetry record, specifying, where appropriate, the incorporations of radionuclides into the body. These doses, as well as doses received from accidental or emergency exposures, shall be recorded in the individual dosimetry history, separately from doses received during normal working conditions.

Article 42. *Dose communication.*

1. Exposed workers who are exposed in more than one activity or installation shall be obliged to expressly report this circumstance to the Head of the Radiation Protection Service or Technical Radiation Protection Unit or, failing this, to the Supervisor or person in charge of the radiation protection functions of each of the centres in which they work, so that their individual dosimetry records may be updated and completed in all of them. To this end, the worker shall report for each activity the dosimetric results provided for the other activities.

2. In the event of a change of employment, the worker shall provide a certified copy of his dosimetric record to the licensee of his/her new post. Where appropriate, as provided for in Chapter VI of this Title, such communication shall be supplemented by the presentation of the radiological pass.

Article 43. *Filing of documents.*

1. The individual dosimetry records of exposed workers, the documents relating to dose assessment and monitoring equipment measures in the cases referred to in Article 39, and the reports concerning the circumstances and measures taken in cases of accidental or emergency exposure, as referred to in Article 38, shall be kept on file by the licensee until the worker reaches or has reached the age of seventy-five years, and never for a period of less than thirty years from the date of cessation of the worker's employment in the activities which led to his classification as an exposed worker.

2. The licensee of the practice shall make this information available to the Nuclear Safety Council and, in accordance with its own competences, to the public administrations, in the cases foreseen in the laws, and to the courts and tribunals that request it.

3. In the event that the exposed worker terminates their employment, the licensee shall provide them with a certified copy of their dosimetry history.

4. Upon definitive termination of any of the practices regulated by these regulations, the licensee shall deliver, to the Nuclear Safety Council and to the health authority, the files referred to in section 1, and shall also deliver to the health authority the clinical and occupational records.

5. In the case of outside workers, the head of the external company to which they report shall be responsible for compliance with the provisions of this Article.

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CHAPTER IV

Medical surveillance of exposed workers

Section 1. Medical *surveillance of exposed workers*

Article 44. *Medical surveillance of exposed workers.*

Medical surveillance of exposed workers shall be based on the general principles of occupational medicine, as well as on the provisions of Law 31/1995, of 8 November 1995, on the Prevention of Occupational Risks, and its implementing regulations.

Article 45. *Medical examinations.*

1. Any person to be classified as a category A exposed worker shall undergo a prior health examination to ascertain his fitness to perform his assigned duties.
2. Exposed category A workers shall, in addition, be subject to periodic medical examinations to ensure that they remain fit for their duties. These examinations shall be carried out every twelve months or more frequently, if it is medically necessary, in the light of the worker's state of health, working conditions or incidents that may occur. They shall be valid for thirteen months.
3. Failure to obtain the medical fitness will result in removal as a category A exposed worker.

Article 46. *Prior medical examination.*

The prior medical examination of any person who is to be assigned to a job involving a risk of exposure such that he is classified as a category A exposed worker shall be aimed at obtaining a clinical-occupational history, including, at least, knowledge of the type of work previously carried out and the risks to which the worker has been exposed as a result thereof and, where appropriate, the dose records which must be provided by the worker.

Article 47. *Periodic medical examinations.*

1. Periodic medical examinations of exposed category A workers shall be adapted to the characteristics of the exposure to ionising radiation or possible internal or external contamination and shall include a general clinical examination and other studies needed to determine the condition of exposed organs and their functions.
2. The Prevention Service that carries out the surveillance and control of the health of workers may determine the advisability of extending, for as long as necessary, the medical surveillance of category A workers who have subsequently been declared unfit or have ceased this professional activity. In cases in which this post-occupational medical surveillance must be carried out by another Prevention Service or by the National Health System, because the worker has changed company or is unemployed or retired, the Prevention Service must inform the worker of this and provide the worker with the necessary information, preferably by means of a copy of the clinical-occupational history.
3. In the case of category A workers who have worked in controlled areas of nuclear facilities, medical surveillance and monitoring shall continue for ten years after cessation of the work.

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Article 48. *Medical classification.*

1. From the medical point of view and according to the results of opportune medical examinations, exposed workers in category A shall be classified as follows:

a) Fit: those who are able to carry out the activities involving the risk of exposure associated with the job.

b) Fit subject to certain conditions: those who can carry out the activities involving the risk of exposure associated with the job, provided that the conditions established for this purpose are met, based on medical criteria.

c) Unfit: those that must be excluded from jobs involving risk of exposure.

2. No worker may be assigned or classified for a specific job as a category A worker unless he is medically classified as fit, or fit under certain conditions, working with ionising radiation.

Article 49. *Medical records.*

1. A medical record shall be opened for each exposed category A worker, which shall be kept up to date so long as the person concerned remains as category A worker and shall contain at least information concerning the nature of the employment, the findings of medical examinations prior to employment or classification as a category A worker, periodic and occasional medical examinations, and the dose record of the person's entire working life.

2. This medical record shall made and shall be retained until the worker r attains or would have attained seventy-five years of age and, in no case, for not less than thirty years after the cessation of the work, in the Prevention Services that carry out the surveillance and control of the health of the workers corresponding to the work centers in which those persons provide or have provided their services, and shall be available to the competent authority and to the worker.

Section 2. Special medical surveillance of exposed workers

Article 50. *Special medical surveillance.*

If any of the dose limits laid down in Article 11 are exceeded or suspected of being exceeded, special medical surveillance shall be carried out. Subsequent exposure conditions shall be subject to the agreement of the Prevention Service that carries out surveillance and control of workers' health. Such conditions shall ensure that the average annual dose of the worker over his working life does not exceed the annual regulatory dose limit.

Article 51. *Additional measures.*

In addition to the medical surveillance described in the previous articles, other measures that the Prevention Service considers appropriate shall be applied, such as further examinations, decontamination measures or urgent therapeutic treatment and, if necessary, medical care and treatment in a center authorised for this purpose in application of Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of health centers, services and establishments. The authorisations granted under this Royal Decree will be communicated to the Ministry of Health and the Nuclear Safety Council. The Ministry of Health shall make available to any interested party an updated list of such centers.

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Section 3. Appeals

Article 52. *Appeals.*

Declarations of fitness to work and appeals against such declarations shall be governed by the provisions of the applicable health and labour legislation.

CHAPTER V

Protection for apprentices and students

Article 53. *Protection for trainees and students.*

1. The exposure conditions and occupational protection of apprentices and students aged over 18 years referred to in Article 13.1 shall, as appropriate, be equivalent to those of exposed workers in category A or B as defined in Article 22.
2. The exposure conditions and occupational protection of apprentices and students aged between sixteen and eighteen years referred to in Article 13.2 shall be equivalent to those of exposed workers in category B as defined in Article 22.1.

CHAPTER VI

Occupational protection of outside workers

Article 54. *Occupational protection of outside workers.*

The individual radiological surveillance system shall provide outside workers with protection equivalent to that for the exposed workers employed on a permanent basis by the licensee, for which purpose the measures established in this chapter shall be adopted.

Article 55. *Obligations of the outside company.*

The outside company is responsible for the radiological protection of its workers in application of the provisions of these regulations and, in particular, shall:

a) Carry out the declaration procedure established in the Ninth Additional Provision, for inclusion in the "Register of Outside Companies" of the Nuclear Safety Council.
b) Respect and ensure respect for the principles and standards of protection laid down in this Regulation, in particular the dose limits.
c) Provide its workers with the information and training relating to radiation protection required in the performance of their work in accordance with Article 23.
d) Control the doses received by their workers in the performance of their work and maintain the dose records in accordance with Articles 39 to 43.
e) Maintain medical surveillance of their workers in accordance with Articles 44 to 49.
f) Request from the Nuclear Safety Council and assign to each exposed worker of category A the radiological passport and keep it always up to date.

Article 56. *Obligations of the licensee of the installation or activity.*

1. The licensee of the installation or activity in whose controlled or supervised area the outside workers carry out activities shall be responsible, within the scope of his activity and competence, for the operational aspects of the radiation protection of these

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workers, ensuring that the principles, standards of protection and dose limits laid down in these regulations and developed in the official documents of the installation are respected.

2. The licensee of the installation or activity shall be obliged to:

a) Prior to the start of activities in a controlled or supervised area, to make sure:

1.º That the company is registered in the "Register of Outside Companies".

2.º That the classification of the outside worker is appropriate in relation to the doses liable to be received at the facility or activity.

3.º That the outside worker has received the required basic training on radiation protection referred to in Article 23.

4.º To Provide specific information and training in relation to the particularities of both the controlled area and the activity to be carried out.

5.º To Provide working instructions on the radiological risk associated with the sources and operations to be carried out in the supervised area.

6.º That the outside worker is provided with individual exposure monitoring appropriate to the nature of the activities, and with any operational dosimetric monitoring that may be necessary.

7.º That the exposed outside worker in category A is certified as medically fit to carry out the activities to which he/she is to be assigned.

8.º That the exposed outside worker in category A is subject to an official individual dosimetric control of his exposure resulting from the activities to be carried out in the facility, which must be appropriate to the characteristics of the activity to be performed. In the case of exposed outside workers in category B, the dose may be estimated in accordance with Article 34.

9.º That the dosimetric data are complete and that the dosimetric conditions of the outside worker are appropriate to the nature of the activity to be performed.

For category A outside workers, in the absence of official dosimetry data, these conditions may be estimated on the basis of operational dosimetry data, which shall be valid for a maximum period of ninety days.

b) During each activity: ensure that the necessary personal protective equipments is available for the outside worker, providing, where appropriate, the specific material to be used in the work area of the controlled area.

c) After the end of the activity: record in the radiological passport, for external exposed category A workers, the data referring to the facility, the period covered by the activity, the estimated occupational dose as a result of the occupational dosimetry monitoring that may have been necessary, and the internal dose determined by the technical services dependent on the licensee, as detailed in Article 58.

Article 57. *Obligations of outside workers.*

All outside workers are obliged to collaborate with those responsible for radiological protection, both of their company and of the licensee of the facility, in their protection against ionising radiation, fulfilling the norms established by them.

Article 58. *Radiological passport.*

1. The radiological passport is a public, personal and non-transferable document, required for exposed outside workers of category A.

2. The radiological passport and its identification number shall be issued by the Nuclear Safety Council. Each worker will have a unique individual document

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the identification number shall be the one initially assigned and shall be maintained on subsequent renewals of the document.

3. The radiological passport shall cover the following aspects:

a) When assigning a document:

1.º Data relating to the identity of the worker, including sex, date of birth and nationality.
2.º Previous dose record of the worker.
3.º Name, address, date of registration and registration number of the company to which the worker belongs at any given time.

b) Before starting an activity in a controlled area:

1.º Medical classification of the worker in accordance with the provisions of these regulations.
2.º Date of the last medical examination.
3.º Up-to-date dose record of the worker.
4.º Basic training data on radiation protection.

c) Data to be included at the end of an activity:

1.º Identification of the facility.
2.º Period covered by the activity.
3.º Dose provisionally assigned by the operational dosimetry system.
4.º Monthly dose assigned by the official dosimetry system. In the case of non-uniform exposure, the dose to the relevant organs or tissues shall be reported.
5.º activity intake and committed dose, in the event that the work may have involved a risk of internal contamination.
6.º Effective dose.

2. The format and content of this document is that established in the Nuclear Safety Council Instruction IS-01, which defines the format and content of the individual radiological monitoring document (radiological passport).

TITLE V

Radiation protection of members of the Public exposures under normal circumstances

SINGLE CHAPTER

Fundamental elements

Article 59. *Basic principles.*

The protection of members of the public shall be ensured by such measures and controls as are necessary to ensure that practices are conducted in accordance with the principles set out in Article 6 and the general principles governing such protection set out in Article 60.

Article 60. *General principles.*

1. The protection of members of the public under normal circumstances shall be based on the following principles:

a) The contribution of practices to the exposure of members of the public should be kept as low as reasonably achievable, taking into account economic and societal factors.

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b) The licensee shall carry out appropriate studies on a case-by-case basis to confirm that the risk of exposure to which members of the public may be subjected as a result of their activities is not significant from the radiation protection point of view, taking into account the long-term effects.

c) The practices shall be designed and implemented in such a way as to avoid or reduce to the lowest reasonably practicable level the release of radioactive effluents into the environment and the generation of radioactive waste, throughout the life cycle of the facility, as well as possible doses arising from exposure to external radiation.

d) On the basis of the studies referred to in paragraph b), the relevant administrative authorisation shall specify whether a specific monitoring system must be in place to assess and control, during the course of the activity, the doses likely to be received by members of the public.

2. Monitoring will be based primarily on the doses likely to be received by members of the public, including long-term health protection and, where justified by the associated risk, on the implementation of an environmental monitoring programme appropriate to the risk and the environments potentially impacted.

Article 61. *Responsibilities.*

1. The licensee shall be responsible for ensuring that all operations are carried out in accordance with Articles 6 and 60 and, in particular, for carrying out the following tasks within its facilities:

a) Achievement and maintenance of an optimal level of protection for the environment and members of the public.

b) Checking the effectiveness and proper maintenance of technical devices for the protection of members of the public.

c) Commissioning of equipment and measurement procedures necessary for the radiation protection of members of the public and, where appropriate, assessment of exposure and radioactive contamination of the environment and members of the public.

d) Calibration, verification and periodic checking of the good condition and functioning of measuring instruments.

2. The performance of these tasks shall be carried out in accordance with established procedures and with the advice and supervision of the Radiation Protection Service or Technical Unit foreseen in Articles 25 and 26 or, failing this, of the Supervisor or person entrusted with the radiation protection functions.

Article 62. Discharges *of radioactive effluents and disposal of solid radioactive waste.*

1. Any discharge of radioactive effluents and disposal of solid radioactive waste into the environment will require express authorisation, subject to a report by the Nuclear Safety Council. The Directorate General for Energy Policy and Mines will be responsible for issuing this authorisation for those facilities whose authorisation is the responsibility of the Ministry for Ecological Transition and the Demographic Challenge; or the Autonomous Communities, for those facilities whose authorisation is their responsibility.

Evacuation shall comply with the limits and conditions established in the aforementioned authorisation, taking into account the characteristics of the practice.

2. To this end, the applicant for authorisation shall attach appropriate studies in each case concerning the release of radioactive effluents into the environment and the capacity of the area to receive radioactive pollutants according to its characteristics, taking into account the relevant demographic, meteorological, geological, hydrological and ecological conditions.

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Article 63. *Radioactive effluent discharge emission levels.*

The activity levels for the discharge of radioactive effluents into the environment shall be such that the activity concentrations of the radionuclides contained therein and the doses likely to be received by members of the public are as low as reasonably achievable, economic and societal factors being taken into account. These levels shall always be lower than the limits specified in Article 15 and, where appropriate, the restrictions established by the Nuclear Safety Council in accordance with Article 9.

Article 64. *Estimation of doses received to the members of the public.*

1. The licensee of each authorised practice shall make an estimation of the doses received to the members of the public from authorised practices. The extent of such arrangements which shall be proportionate to the risk of exposure risk involved arising from the practice.
2. The Nuclear Safety Council shall determine those practices for which a dose assessment to members of the public is required in a realistic way and those for which a screening assessment is sufficient.
3. In the case of nuclear facilities and radioactive facilities in the nuclear fuel cycle, this estimate shall be made at least annually, taking into account:

a) The information available to identify the representative person of the members of the public, taking into account the effective pathways of transmission of radioactive substances.
b) The assessment of doses due to external radiation, indicating, as where appropriate, the type and quality of radiation in question.
c) The assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their and the physical and chemical states of the radionuclides, and the determination of the activity concentrations of these radionuclides in food and drinking water or other relevant components of the environmental media.

4. The licensee of each practice shall submit the results of the dose estimates to the Nuclear Safety Council.

Article 65. *Archive of documentation and information for members of the public.*

1. The licensee shall keep records of the measurement of external exposure and estimates of radionuclide intake and radioactive contamination, as well as the results of the assessment of doses received by the representative person throughout the life of the installation.
2. The Nuclear Safety Council shall make available on request to the stakeholders relating to the results of the documentation submitted to it pursuant to Article 64.4 available to the interested parties.

Article 66. *Equipment in relation to effluents and solid radioactive waste.*

1. Practices that may give rise to effluents and solid radioactive waste that present a significant radiological hazard will be equipped with the necessary independent and specific systems for storage, treatment and, where appropriate, disposal, the operation of which will be adequately checked to prevent uncontrolled or unplanned discharges.
2. The storage of radioactive waste shall be carried out by confining it in containers whose characteristics provide sufficient protection against ionising radiation, taking into account the conditions of the storage site and the possible dispersion or leakage of the radioactive material.
3. Receptacles containing radioactive waste shall be appropriately marked.

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4. The licensee shall also keep a register in which the most relevant physico-chemical data on the contents and, as a minimum, the maximum values of the exposure level on contact and at a distance of 1 metre from the surface, as well as the date of the last measurement and, if possible, the activity, shall be recorded for each container.

TITLE VI

Emergency exposure situations

SINGLE CHAPTER

Interventions

Article 67. *General principles.*

1. This Title shall apply to any intervention in nuclear or radiological emergencies, including advance planning and preparation.
2. The directors of the Article 68 plans and the Nuclear Safety Council shall ensure that the following principles are observed in the implementation and magnitude of interventions in emergency exposure situations:

a) The form, magnitude and duration of the intervention should be optimised so as to maximise the benefit corresponding to the reduction in health detriment, once considered the harm associated with the intervention.
b) The dose limits in accordance with Articles 10 to 15 shall not apply in the event of intervention in nuclear or radiological emergencies.

3. The Nuclear Safety Council shall establish reference levels for emergency exposure situations. Optimisation of protection shall give priority to exposures above the reference level and shall continue to apply below the reference level. Reference levels shall be established taking into account both radiation protection requirements and social criteria.

Article 68. *Intervention in the event of a nuclear or radiological emergency.*

1. The actions to be taken in nuclear power plant emergency situations will be those established in the on-site emergency plans, as well as in the appropriate off-site emergency plans, derived from the civil protection plans for nuclear emergencies.
2. For the rest of the nuclear and radioactive facilities, and for activities other than those mentioned above, the actions to be taken shall be those established both in the on-site emergency or self-protection plans of each facility or activity and in the Special Plans of the Autonomous Communities for radiological emergencies and in the State Civil Protection Plan for radiological risk, derived from the Basic Directive on planning for Civil Protection against Radiological Risk.
3. The actions to be carried out in emergency situations in the transport of Class 7 dangerous goods by road and rail will be those established in the Special Civil Protection Plans against the risk of accidents in the transport of dangerous goods by road and rail, derived from the Basic Directive on Civil Protection planning against the risk of accidents in the transport of dangerous goods by road and rail.

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Article 69. *Exposure of emergency workers.*

1. The Nuclear Safety Council shall establish reference levels for the exposure of emergency workers. These levels shall, wherever possible, be kept below the dose limits laid down in Article 11.

2. In situations where compliance with paragraph 1 is not possible, the following conditions shall apply:

a) Reference levels for exposure of emergency workers will generally be set below an effective dose of 100 mSv.

b) In exceptional situations, and in order to save lives, to avoid severe radiation-related health effects, or to prevent the development of catastrophic conditions, a reference level for an effective external radiation dose to emergency workers above 100 mSv, but not exceeding 500 mSv, may be established.

3. Pregnant or breastfeeding women involved in nuclear or radiological emergency response activities shall, for the purposes of the doses and radioactive contamination they may receive during their intervention, be considered as members of the public in a non-emergency situation.

4. Emergency workers involved in an intervention in the event of a nuclear or radiological emergency shall be subject to dosimetry control and special medical surveillance in accordance with the provisions of Article 50, which shall be specifically developed in the applicable standards.

5. Organisations involved in responding to nuclear or radiological emergencies, as set out in on- and off-site nuclear emergency plans shall ensure that emergency workers have been clearly and comprehensively informed in advance of the associated health risks and of the protective measures available. They shall also provide such personnel with appropriate training as provided for in the emergency management system, which may include practical exercises.

6. Tasks performed by emergency workers where an effective dose of 100 mSv may be exceeded should be performed on a voluntary basis.

Article 70. *Exposure of members of the public in emergency.*

1. Without prejudice to the reference levels established for equivalent doses, the Nuclear Safety Council shall establish reference levels expressed in terms of effective doses in the range from 20 to 100 mSv (acute or annual) for members of the public in emergency exposure situations.

2. In specific situations, a reference level below the range referred to in paragraph 1 may be considered. In particular, a reference level below 20 mSv may be set during an emergency exposure situation where adequate protection of members of the public can be provided without either disproportionate harm due to the protective measures or excessive cost.

3. The Nuclear Safety Council shall establish radiological criteria for the transition from an emergency exposure situation to an existing exposure situation and for lifting of long-term protective measures, such as relocation.

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TITLE VII

Existing exposure situations

CHAPTER I

Optimisation of radiation protection

Article 71. *Optimisation of protection.*

In existing exposure situations, such as those described in Annex V:

a) The Nuclear Safety Council shall establish specific reference levels in cases not covered by Article 72, when a situation is identified which may give rise to a significant risk from the radiation protection point of view. These reference levels expressed in terms of effective dose will be in the range of 1 to 20 mSv/year.

b) Optimisation of protection shall give priority to exposures above the reference level and shall continue to apply below the reference level.

c) In setting the reference levels in subparagraph a), account shall be taken both of radiation protection requirements and of social criteria and the characteristics of the prevailing situations.

d) The Nuclear Safety Council shall determine the need to establish an environmental radiological surveillance programme in the cases specified in Annex V, paragraph 1.

Article 72. *Reference levels.*

The following reference levels are established:

a) For indoor exposure to radon, 300 Bq/m3in terms of the annual average radon concentration in air, both for dwellings or publicly accessible buildings and for workplaces.

b) For outdoor exposure in enclosed areas to gamma radiation from building materials, 1 mSv per year, in addition to outdoor exposure in the open air.

CHAPTER II

Interventions

Article 73. *General principles.*

Interventions in existing exposure situations shall be carried out in accordance with the following principles:

a) An intervention shall only be undertaken when the reduction of health detriment due to radiation is sufficient to justify the harmful effects and the costs of the intervention, including the social costs.

b) The form, magnitude and duration of the intervention should be optimised so as to maximise the benefit corresponding to the reduction in health detriment, net of the harm associated with the intervention.

c) Interventions shall be subject to the requirements applicable to planned exposures, and the dose limits laid down in Articles 11 and 15 respectively shall apply to members of the public and workers carrying out the interventions.

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Article 74. *Intervention in contaminated areas.*

1. In situations of existing exposure due to the contaminated areas listed in Annex V.1, and depending on the risks involved in the exposure, the person responsible for the intervention, in accordance with the applicable standards, following a favourable report from the Nuclear Safety Council, shall:

a) Delimit the affected area and identify the affected members of the public.
b) Consider the need for and extent of protection measures to be applied to the areas and members of the public concerned.
c) Implement an exposure monitoring system and assess the exposure of different groups of members of the public.
d) Make appropriate interventions taking into account the characteristics of the situation.
e) Regulate access to and use of land or buildings within the defined area.
f) Carry out a radiological study in order to characterise the state of the land after the completion of the actions included in the intervention.

2. Once the intervention has been completed, the Nuclear Safety Council:

a) Shall evaluate the radiological survey required in paragraph 1(f) and, if necessary, inspect the area to verify the results of the survey.
b) It shall issue an opinion, where appropriate, determining whether the corresponding limitations on the use of those lands or resources affected are appropriate, and shall forward this opinion to the Ministry for Ecological Transition and the Demographic Challenge, in order to ensure compliance.

CHAPTER III

Radon exposure

Section 1.1 Workplaces requirements

Article 75. *Licensee's obligations.*

1. Licensees of work activities in the workplaces listed below shall estimate the annual average airborne radon concentration in all areas of the workplace in which workers are required to remain or to which they have access by reason of their work, excluding outdoor areas:

a) underground workplaces, such as construction sites, tunnels, mines or caves.

b) where groundwater is processed, handled or exploited, such as thermal activities and spas.

c) All workplaces located on the ground floor or basement level in the priority municipalities referred to in Article 79.

2. Where a workplace contains areas with airborne radon concentrations that, on an annual average, exceed the reference level of 300 Bq/m3 Bq/m^3, the licensee of the work activity shall take appropriate measures to reduce radon concentrations reducing measures and/or exposure in accordance with the principle of optimisation, after which the annual average airborne radon concentration in the workplace shall be reassessed.

3. places where, despite the actions taken in accordance with paragraph 2, airborne radon concentrations in any of the areas of the within workplaces specified in paragraph 1 continue to exceed, as on an annual average basis, a level of radon in the air which is higher greater than

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the reference level of 300 $Bq_{/m3}$, the licensee is subject to compliance with Article 19 and other applicable Articles.

Article 76. *Estimation of radon annual average activity concentration in air.*

1. The estimates of the annual average airborne radon concentration required by Article 75 shall be undertaken by the licensee of the workplace activity, who may be advised by a Radiation Protection Technical Unit.

2. The radon annual average airborne activity concentration shall be estimated from long-term measurements following the Guidelines and Instructions issued by the Nuclear Safety Council. The laboratory performing the measurement shall be accredited in accordance with Standard UNE-EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, or subsequent revision, by the National Accreditation Body (ENAC), or by another national accreditation body designated in accordance with European regulations. The licensee of the workplace activity shall be responsible for verifying that the measuring laboratory has a valid accreditation.

3. The results of the estimates of the radon annual average activity radon air concentration in air shall be set out in a report which shall identify the author(s), indicating their position in the company or contractual relationship, and which shall state the date of completion and signature. This report must be drawn up by the licensee of the workplace activity, the workers designated by the latter, an in-house prevention service, an external prevention service or, in the cases established by the Nuclear Safety Council, a Technical Radiation Protection Unit. This is without prejudice to the responsibility of the licensee to ensure the protection of workers. The report shall be available to the worker, to the health authorities, to the Labour and Social Security Inspectorate or, where appropriate, to other public administrations competent in labour matters, and to the Nuclear Safety Council.

Section 2.a National radon action plan

Article 77. *Establishment of the National Radon action Plan.*

1. The Government will establish the policy to reduce the risk to the health of the population due to indoor radon exposure by approving the National Radon Action Plan. The Plan will be proposed by the Ministry of Health and updated every five years.

2. The National Radon Action Plan shall include measures to promote the identification of dwellings, publicly accessible buildings with public access and workplaces where the annual average radon concentration exceeds the reference level set out in Article 72 a), for any source taking into account any possible pathways of radon ingress, whether soil, tap water or building materials, and to encourage, where appropriate by technical or other means, radon concentration-reducing measures. The National Radon Plan shall cover the aspects listed in Annex VIII.

3. The National Radon Plan will include the strategies established and the activities to be carried out by the different public administrations in order to reduce the risk to the health of the population due to exposure to radon. In this respect, the Autonomous Communities and local entities, within the scope of their respective competences and within the framework of the National Plan, can draw up their own plans.

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Article 78. *National Radon Plan Committee.*

1. The National Radon Plan Committee is created, attached to the Ministry of Health, made up of representatives of the authorities with competence in the matters covered by the Plan, with the following composition:

a) Chairmanship: a representative of the Ministry of Health, with the rank of Director General.
b) Vice-presidency: a person representing the Nuclear Safety Council, with the rank of Technical Director.
c) Members: shall be members of the Committee:

1.º Eight persons holding posts of at least the rank of Head of Area or similar, representing each of the following ministerial departments: Two representatives from the Ministry of Health; two representatives from the Ministry of Ecological Transition and Demographic Challenge; two representatives from the Ministry of Transport, Mobility and Urban Agenda; two representatives from the Ministry of Labour and Social Economy.
2.º Two representatives of the Nuclear Safety Council, assigned to posts of at least the rank of Head of Area or similar.
3.º One representative from each autonomous community and city with a Statute of Autonomy that is interested in participating, with a rank of at least Deputy Director General or similar.
4.º Three representatives of local bodies, appointed by the Spanish Federation of Municipalities and Provinces.

2. The bodies appointing the members of the Committee shall simultaneously appoint their alternates, according to the same criteria as those referred to in paragraph 1.
3. The Secretariat of the National Radon Plan Committee shall be provided by a civil servant appointed by the Ministry of Health, who shall not be considered a member of the Committee. In the event of absence, vacancy or illness, a civil servant designated by the latter Ministry shall deputise.
4. The functions of this Committee are as follows:

a) Draw up the National Radon Plan and submit it to the Ministry of Health for approval by the Government.
b) Update the National Radon Plan every five years, in accordance with scientific knowledge and the progress made in the measures included in it, and submit these updates to the Ministry of Health for approval by the Government.
c) Promote, evaluate and supervise compliance with the action guidelines set out in the Plan.
d) To act as a liaison body between the ministerial departments and attached bodies and the regional and local administrations, in order to ensure the coordination of the criteria and policies defined by them.

5. The National Radon Plan Committee shall be set up within one month of the entry into force of this Royal Decree and shall meet when required for the performance of its functions, and at least every two years.
6. The National Radon Plan Committee may set up a working group made up of representatives of the ministries members of the National Radon Plan Committee and the Nuclear Safety Council to discuss and draw up proposals to be submitted to the National Radon Plan Committee. This working group may include the participation of such experts as it may convene.

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7. The National Radon Plan Committee may invite to participate in its meetings or parts thereof, with the right to speak but not to vote, as many experts as it deems appropriate.

8. Without prejudice to the provisions established in this Royal Decree, the functioning of the Committee shall be in accordance with the provisions on collegiate bodies in articles 15 to 22, both inclusive, of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector, with regard to its convening, as well as its system of constitution, the adoption of agreements, the holding of meetings and the substitution of its members.

9. The meetings of the Committee and the working group may be held both in person and remotely, in the terms provided for in article 17.1 of Law 40/2015, of 1 October.

10. The creation and operation of the Committee and, where appropriate, of the working group, will not entail an increase in public expenditure and will be met with the personal, technical and budgetary resources of the Ministry of Health.

Article 79. *List of priority municipalities for action.*

The Nuclear Safety Council shall publish, on the basis of the best available information, an instruction containing a nationwide list of municipalities in which a significant number of buildings exceed the reference level set out in Article 72.a). This list will be updated periodically, by means of an Instruction of the Nuclear Safety Council, depending on the state of progress of the National Radon Plan and on the new data available.

CHAPTER IV

Exposure to gamma radiation emitted by building materials

Article 80. *Obligations of suppliers of building materials.*

1. Suppliers of building materials listed in Annex VI shall, before placing them on the market, determine the radioactive content of the building materials (Ra-226; Th-232 and K-40) in order to ensure compliance with the reference level laid down in Article 72.b). The determinations shall be made in accordance with guidelines established by the Nuclear Safety Council, and the results shall be made available to the Nuclear Safety Council and to the competent authority for the placing on the market of these materials.

2. The reference level set out in Article 72.b) shall be deemed to be met where the value of the I_C index is less than 1 or, alternatively, and in the case of materials used as cladding or insulation, where the value of the I_D index is less than 1. These indices are calculated in accordance with Annex VII.

3. For building materials which do not satisfy the requirements specified in paragraph 2, with the exception of those intended to be used exclusively as external cladding, specific requirements and restrictions on their use in buildings may be laid down where they may affect the external gamma radiation dose received by the occupants of the building, so as to ensure compliance with the reference level. These restrictions shall be determined on the basis of a detailed dose calculation, according to UNE-CEN/TR 17113:2017, Construction products. Assessment of the release of hazardous substances. Radiation emitted by building materials. Dose assessment due to gamma radiation (Ratified by the Spanish Association for Standardisation in January 2018), or subsequent revision.

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CHAPTER V

Aircraft crew

Article 81. *Obligations of airlines.*

Airlines shall establish a radiation protection programme when cosmic radiation exposures to the crew could result in a dose in excess of 1 mSv per official year. This programme shall cover, in particular:

a) Exposure assessment of the crew using appropriate codes to model the cosmic radiation field.
b) Organisation of working schedules in order to reduce exposure for the most exposed crew members.
c) Information to the workers concerned on the radiological risks associated with their work.
d) Application of Article 12 to female air crew.

TITLE VIII

Inspection and sanctioning regime

CHAPTER I

Inspection regime

Article 82. *Inspection regime.*

1. All practices, activities and other exposure situations, as well as entities, included within the scope of application of this regulation shall be subject to the inspection regime established in the eighth additional provision, to be carried out by the Nuclear Safety Council, without prejudice to the competences of other authorities in relation to these practices, activities, exposure situations and entities.
2. Without prejudice to the provisions of section 1, the Labour and Social Security Inspectorate, as well as other public administrations competent in labour matters, as referred to in article 7.2 of Law 31/1995, of 8 November, on the Occupational Risks Prevention , shall collaborate with the Nuclear Safety Council in monitoring compliance with the obligations of the licensees of work activities with exposure to radon, as detailed in section 3, in the case of work centres or workplaces that are included within their respective fields of competences
3. The purpose of such collaboration shall be to bring to the attention of the Nuclear Safety Council:

a) Any possible breaches of the obligations concerning the estimates of the annual average radon concentration laid down in Article 75.1;
b) if the above estimates indicate that the reference level provided for in Article 75.2 is exceeded;
c) verification that the laboratory performing the required radon concentration measurements has a current accreditation in accordance with Article 76.2;
d) possible breaches concerning the availability of the report provided for in Article 76.3.

To this end, the Labour and Social Security Inspectorate or, where appropriate, the public administration competent in labour matters, shall forward to the Nuclear Safety Council any complaints or communications received in relation to the above points, and the information obtained by the officials of these bodies

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institutions in the course of their inspection duties arising from their own activities in the field of health and safety at work.

CHAPTER II

Sanctioning regime

Article 83. *Infringements and Penalties.*

Without prejudice to the civil, criminal or other liabilities that may be incurred by the licensees of practices and activities regulated in these regulations, failure to comply with the provisions of these regulations shall constitute the infringements and penalties provided for in Chapter XIV of the Nuclear Energy Act 25/1964, of 29 April. The exercise of the sanctioning powers provided for in paragraph 1 shall correspond to the competent bodies of the General State Administration or of the Autonomous Communities within the scope of their respective competences.

TITLE IX

Competent authorities

SINGLE CHAPTER

Competent authorities

Article 84. *Competent authorities.*

The application of the provisions of this regulation is the responsibility of the following competent authorities:

a) Ministry of Defence

Both in the case of military activities involving radiological risk, and with regard to the intervention of the personnel of the NBQ Defence Units or the personnel of the Military Emergency Unit (UME) in nuclear or radiological emergencies, the competence for the application of the provisions of this regulation lies with the Central Radiological Protection Board of the Ministry of Defence.

b) Ministry of Interior.

1.º Drawing up of nuclear civil protection plans for nuclear emergencies., as well as Basic Planning Guidelines and, where appropriate, state plans, in the event of civil radiological risk and the risk of accidents in the transport of dangerous goods by road and rail, in accordance with Article 68.

2.º Exercise of the functions of point of contact with other Member States for the purposes of mutual assistance in relation to actions in the event of a nuclear or radiological emergency, in accordance with the fifth Additional Provision.

3.º Application of the provisions of these regulations in relation to the intervention of personnel from the Nuclear, Radiological, Biological and Chemical (NRBQ) defence units of the National Police and the Civil Guard in nuclear or radiological emergencies.

c) Ministry of Transport, Mobility and Urban Agenda.

Establishment of the basic quality requirements for buildings with regard to compliance with the reference level set out in this regulation for the average

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annual radon concentration In air_T incorporating them into the Technical Building Code, in accordance with the provisions of the Third Additional Provision.

d) Ministry of Labour and Social Economy.

Collaboration with the Nuclear Safety Council in the monitoring of compliance with the obligations foreseen for the licensees of work activities with exposure to radon in articles 75 and 76 in the case of work centres or workplaces included within its scope of action, in accordance with articles 82.2 and 82.3.

e) Ministry for Ecological Transition and the Demographic Challenge.

1.º Authorisation of the practices in accordance with Article 7, by resolution of the Directorate General for Energy Policy and Mines, in accordance with the provisions of the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December.

2.º Authorisation, by resolution of the Directorate General for Energy Policy and Mines, of all practices that make use of non-medical imaging procedures, in accordance with Article 8.

3.º Establishment, by resolution of the Directorate General for Energy Policy and Mines, of the individual dose restriction that members of the public may receive due to the planned use of a specific radiation source, in accordance with Article 9.3.

4.º Express authorisation, by resolution of the Directorate General for Energy Policy and Mines, of any discharge of radioactive effluents and disposal o f solid radioactive waste into the environment, in accordance with Article 62, of those facilities whose authorisation falls within the competence of this ministry.

5.º Guarantee compliance with the limitations on the use of land or resources affected by contamination, in accordance with Article 74.2.b).

6.º Exercise of the functions of contact point with other Member States with regard to consumer products, in accordance with the Fifth Additional Provision.

f) Ministry of Health.

1.º Maintenance of the catalogue and general register of the approved centres referred to in

2.º Proposal to the Government of the National Action Plan against Radon, in accordance with Article 78.

3.º Exercise of the functions of contact point with other Member States in the medical field, in accordance with the Fifth Additional Provision.

g) Nuclear Safety Council.

1.º Preparation of prior reports in the cases established in these regulations.

2.º Proposal to review existing classes or types of practices from the point of view of their justification, whenever significant new evidence of their efficiency or consequences emerges, in accordance with Article 7.2.

3. Controlling the dose restrictions established by the licensee in accordance with Article 9.1 and 9.2.

4.º Ensure that any individual dose constraints that members of the public may receive, due to the planned use of a specific radiation source, are consistent with the dose limit for the sum to the same person of the doses due to all authorised practices, in accordance with Article 9.3.

5.º Propose guidance to enable the practice licensee to establish dose constraints in accordance with Article 9(4).

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6.º Authorisation, in exceptional situations, excluding nuclear or radiological emergencies, of individual occupational exposures in excess of the dose limits laid down in Article 11, in accordance with Article 14.

7.º Authorisation of the use of dose estimation methods in accordance with Article 16.

8.º Authorisation of Radiation Protection Services and Technical Units, in accordance with Article 26.

9.º Issue of the diploma of Head of Radiological Protection Service or Technical Unit, in accordance with Article 27.1.

10.º Establishment of the format and content of the radiological passport, and issue of this document with its identification number, in accordance with Article 58.

11.º Establishment of restrictions on the levels of discharging of radioactive effluents into the environment, in accordance with Article 63.

12.º Identification of practices for which a dose assessment for members of the public is required and those for which an exploratory assessment is sufficient in accordance with Article 64.2.

13.º Making available to interested parties the results of the measurement of external exposure and estimate of radionuclide intake and radioactive contamination, as well as the results of the assessment of doses received by members of the public, in accordance with Article 65.2.

14.º Establishment of reference levels for emergency exposure situations in accordance with Article 67.3.

15.º Establishment of reference levels for the exposure of emergency workers in accordance with Article 69.

16.º Establishment of reference levels for existing exposure situations in accordance with Article 71.a).

17.º Determination of the need to establish an environmental radiological monitoring programme in cases of existing exposure, in accordance with article 71.d).

18. conducting inspections of all practices, activities and other exposure situations, as well as entities of this regulation, in accordance with Article 82.1.

19.º Exercise of the functions of contact point with other Member States in relation to this regulation, in accordance with the Fifth Additional Provision.

First additional Provision. *Occupational risk prevention.*

In matters of worker protection, the rules contained in Law 31/1995, of 8 November, on Occupational Risks Prevention, and the regulations that develop it, shall be applicable, without prejudice to the provisions of these regulations.

Second additional Provision. *Transport of radioactive material*

The transport of radioactive material, in all matters not expressly regulated by its specific regulations, shall be governed by these regulations as far as they are applicable.

Third additional Provision. *Technical Building Code.*

The basic quality requirements for buildings and their facilities, with regard to compliance with the reference level established in this regulation for the annual average radon concentration in air, shall be those determined by the Technical Building Code.

Forth additional Provision. *Personal data protection*

The processing of personal data within the framework of this regulation shall comply with the provisions of Organic Law 3/2018, of 5 December, on the Protection of

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Personal Data and guaranteeing digital rights, and in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC.

Fifth additional provision. *Contact point with other Member States.*

1. The Nuclear Safety Council is designated as the contact point for communications with other Member States in relation to this regulation, the Ministry for Ecological Transition and Demographic Challenge in relation to consumer products, the Ministry of Health in relation to the medical field, and the Ministry of Interior for mutual assistance in relation to actions in the event of a nuclear or radiological emergency.

2. The contact details of the above bodies, including their addresses, as well as their respective areas of competence, will be forwarded to the European Commission. Any changes to this information must also be communicated to the European Commission.

Sixth additional provision. *Collaboration on the monitoring of radon exposure in the workplaces between the Nuclear Safety Council and the Labour and Social Security Inspectorate, and between the Nuclear Safety Council and other public administrations competent in labour matters.*

In order to carry out the actions contemplated in articles 82.2 and 82.3, the Nuclear Safety Council may sign instruments of collaboration with the Labour and Social Security Inspectorate, as well as with other public administrations competent in labour matters, as referred to in article 7.2 of Law 31/1995, of 8 November, on the Prevention of Occupational Risks.

Seventh additional provision. *Declaration and registration of workplaces activities with exposure to natural radiation.*

1. The licensees of the following workplaces occupational activities are required to declare their activity to the competent bodies of the Autonomous Communities in whose territory the activity is carried out, and to perform the studies required to determine whether the workplace activity might give rise to a significant radiological risk for the workers or for members of the public, and to establish, on the basis of these studies, the radiological protection measures and controls specified in this regulation:

a) Industrial sectors involving exposure to naturally occurring radioactive material, including associated secondary processes;

b) storage, handling or disposal of waste NORM;

c) those taking place in workplaces specified in Article 75.1.a) and 75.1.b);

d) those taking place in workplaces specified in Article 75.1.c) where, despite the measures taken in accordance with Article 75.2, they continue to exceed on an annual average basis the reference level laid down in Article 72.a).

2. The competent bodies of the Autonomous Communities shall include the declared workplaces activities in the "Register of occupational workplaces activities with exposure to natural radiation", communicating this information to the Nuclear Safety Council and to the Directorate General for Energy Policy and Mines, which shall keep a Central Register.

3. The declaration of workplaces activities and the studies and establishment of radiation protection measures and controls referred to in paragraph 1 shall be carried out in accordance with the instructions and guidelines issued by the Nuclear Safety Council.

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4. In the case of workplaces activities involving exposure to cosmic radiation during the operation of aircraft, no declaration of the activity is required since the activity is considered to be carried out at the moment when an air carrier applies for authorisation to the State Aviation Safety Agency which, in this field, is the competent authority. The State Aviation Safety Agency shall keep the Nuclear Safety Council informed of the list of air carriers authorised to operate commercially in Spain.

Eighth additional provision. *Inspection regime and obligations of the licensee.*

1. The Nuclear Safety Council Inspectorate will be responsible for verifying compliance with the legal provisions and with all those specifications relating to radiation protection that have been established in the corresponding regulatory authorisations.
2. The Nuclear Safety Council shall inspect the Radiation Protection Services or Technical Units and the Personal Dosimetry Services in order to guarantee that the conditions under which they were authorised and the suitability of their activities are maintained.
3. The result of the inspections shall be recorded in minutes.
4. In accordance with their status as agents of the authority in accordance with the provisions of the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December, the Inspectors of the Nuclear Safety Council shall be considered to be agents of the authority in all matters relating to the performance of their duties.
5. The licensee of all practices and activities included in the scope of application of these regulations, as well as of Radiation Protection Services and Technical Units and Personal Dosimetry Services, shall be obliged to allow or provide the Nuclear Safety Council Inspection:

a) Access to places that inspectors deem necessary for the performance of their duties.
b) The installation of the equipment or instrumentation required for the performance of the necessary tests and checks.
c) The information, documentation, equipment and existing elements that are necessary for the fulfilment of its mission.
d) The collection of sufficient samples to carry out the relevant analyses and checks. If the licensee of the practice so requests, a duly sealed and marked control sample shall be left in his possession.

6. The Inspectors of the Nuclear Safety Council are empowered to require the immediate suspension of practices which, being carried out without observing the provisions of these regulations, involve, in their opinion, a clear threat to persons or the environment. Such proceedings shall be recorded in the minutes with the necessary details.

Ninth additional provision. *Procedure for declaring the activities to be carried out by external companies.*

1. The companies referred to in Article 55 shall submit the declaration as an external company for inclusion in the "Register of External Companies" existing at the Nuclear Safety Council, providing the following information:

a) Company identification.
b) Company name.
c) Tax Identification Number.
d) Activity carried out.

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e) Sworn declaration that they have the technical and human resources, which may be their own or contracted, as well as sufficient knowledge to comply with the provisions of the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December, insofar as it is applicable to them.

2. Any modification of the information provided must be documented to the "Register of External Companies".

3. The Nuclear Safety Council may automatically remove a company from this register if it is in serious non-compliance with the regulations or if it has been inactive for more than five years.

First transitional provision. *Validity of existing authorisations.*

Until their expiry date, the authorisations required by this Regulation which are in force at the time of its entry into force shall remain valid. For subsequent renewals, the provisions of these regulations shall apply.

Second transitional provision. *Dose limits for the eye lens.*

The new dose limits for the eye lens established in articles 11.2.a) and 13.2.a) will be applicable eighteen months after the entry into force of this regulation, and until then the limits established in the Regulation on health protection against ionising radiation, approved by Royal Decree 783/2001, of 6 July, must be used.

Third transitional provision. *Estimation of doses from internal exposure.*

For the estimation of doses due to internal exposure, the dose coefficients appearing in Annex III of the Regulation on health protection against ionising radiation, approved by Royal Decree 783/2001, of 6 July, shall be applicable until such time as the Nuclear Safety Council decides to update them, in accordance with the provisions of paragraph 2 of Annex III of this Regulation.

Fourth transitional provision. *Personal radon dosimetry services.*

During a period of one year from the entry into force of this regulation, those laboratories accredited according to UNE-EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, or subsequent revision, for the trace radon ? measurements , which have submitted to the Nuclear Safety Council the request for authorisation as a personal dosimetry service, attaching the corresponding technical documentation, may operate as personal radon dosimetry services.

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ANNEX I

Dosimetric quantities in the field of radiation protection. Radiation and tissue weighting factors. Operational quantities for the assessment of doses from external exposure

1. Dosimetric quantities in the field of radiation protection:

− Absorbed dose at a point, D: It is the basic physical quantity in radiation protection and is defined as the quotient of the mean energy imparted (dε)by ionising radiation in a volume element and the mass of that element (dm).

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

The unit for absorbed dose is the joule per kilogram (J/kg), and is given the special name of gray (Gy).

− Average absorbed dose in an organ or tissue D_T: is the averaged absorbed dose over an organ or tissue T and is given by the quotient of the total mean energy imparted on that organ or tissue ($\in_T$) and the mass of that organ or tissue (m_T):

$$D_T = \frac{\epsilon_T}{m_T}$$

The unit for the average absorbed dose is the joule per kilogram (J/kg) and is given the special name of grey (Gy).

− Equivalent dose, H_T: is the average absorbed dose to an organ or tissue T weighted by a factor (w_R) that is a function of the type and quality of radiation involved (R):

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

The sum extends to all types of radiation involved. The unit for the equivalent dose is the joule per kilogram (J/kg), and is given the special name of sievert (Sv).

Section 2 shows the values of the radiation weighting factors (w_R) to be used in the calculation of the equivalent dose.

− Effective dose, E: is the sum of the equivalent doses (H_T) in all the organs and tissues of the body weighted by a factor (w_T), depending on the organ or tissue irradiated. It is given by the following expression:

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

The unit for effective dose is the joule per kilogram (J/kg), which is given the special name of sievert (Sv).

The values of the tissue weighting factors (w_T) to be used in the calculation of the effective dose are shown in section 2.

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2. Radiation and tissue weighting factor values.

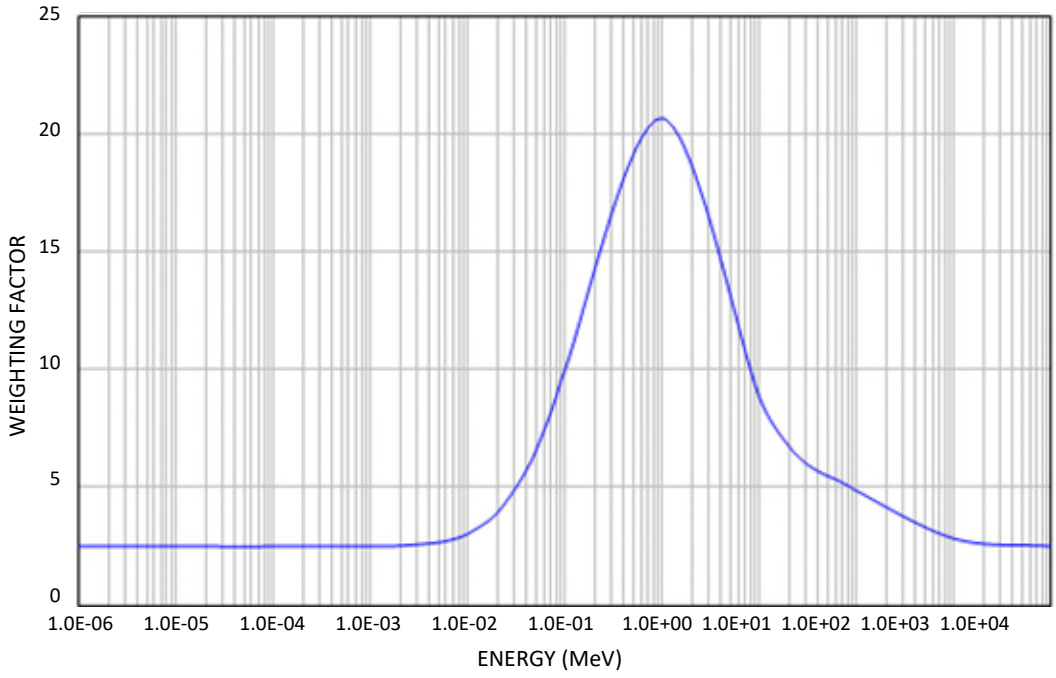
The table below shows the values of the radiation weighting factors (w_R) to be used in the calculation of the equivalent dose.

Table I-1. Radiation weighting factors (w_R)

Energy type and range	w_R
Photons.	1
Electrons and muons.	1
Charged protons and pions.	2
Alpha particles, fission fragments and heavy ions.	20
Neutrons.	See explanation

Note: In the case of external exposure, the values relate to the radiation incident on the body and, in the case of internal exposure, to the radiation emitted from the source.

The radiation weighting factor for neutrons has an energy dependence that conforms to the continuous function shown in the figure below:



This continuous function can be expressed mathematically by the following equations:

$$w_R = 2.5 + 18.2\, e^{-[\ln(E)]_2/6} \quad \text{for } E < 1 \text{ MeV}$$

$$w_R = 5.0 + 17.0\, e^{-[\ln(2E)2/6} \quad \text{for } 1 \text{ MeV} \leq E \leq 50 \text{ MeV}$$

$$w_R = 2{,}5 + 3.25\, e^{-[\ln(0.04E)2/6} \quad \text{for } E > 50 \text{ MeV}$$

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The table below shows the values of the tissue weighting factors (w_T) to be used in the calculation of the effective dose:

Table I-2. Tissue weighting factors (w_T)

Organ or tissue	w_T	$\Sigma w_{T(1)}$
Bone marrow, colon, lung, stomach, breast.	0.12	0.60
Gonads.	0.08	0.08
Bladder, oesophagus, liver, thyroid.	0.04	0.16
Bone surface, brain, salivary glands, skin.	0.01	0.04
Other tissues(2).	0.12	0.12

(1) The w_T factors represent the relative contribution of each organ or tissue to the health detriment resulting from a total exposure of the organism and therefore these weighting factors should sum to 1.

(2) The following tissues are included (14 in total adremals, extra-thoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus and uterus.

The w_T values have been established on the basis of a reference population with equal number of members of each sex and a wide age range, and therefore, for the calculation of the effective dose, these values are applicable to both exposed workers and members of the public of both sexes.

Tissue weighting factors are a tool to be used only for radiation protection purposes and should therefore not be used for other purposes such as judging a possible cause-effect relationship between radiation exposure and the occurrence of certain diseases.

3. Operational quantities for the assessment of doses from external exposure.

In exposure to external radiation fields, it is not feasible to physically measure the dosimetric quantities (effective dose and equivalent dose) on which the dose limits established in the radiation protection system are based.

Thus, the following operational quantities are used to verify and control compliance with the above mentioned limits:

− Personal dose equivalent, Hp(d): operational quantity for individual monitoring and defined as the dose equivalent in soft tissue at an appropriate depth (d) below a specified point on the human body.

The unit for the personal dose equivalent is the joule per kilogram (J/kg), and is given the special name of sievert (Sv).

− Ambient dose equivalent, H*(10): operational quantity for area monitoring and defined as the dose equivalent at a point in a radiation field that would be produced by the corresponding aligned and expanded field in the ICRU sphere at a depth of 10 mm and on the radius vector opposing the direction of the aligned field.

The unit for the ambient dose equivalent is the joule per kilogram (J/kg), and is given the special name of sievert (Sv).

− Directional dose equivalent, H'(d,Ω): operational quantity used in area monitoring and defined as the dose equivalent

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at a point in a radiation field that would be produced by the corresponding expanded field in the ICRU sphere at a depth, d on a radius in a specified direction Ω.

The unit for the directional dose equivalent is the joule per kilogram (J/kg), and is given the special name of sievert (Sv).

Operational quantities are determined from directly measurable physical quantities using conversion factors whose values are established and updated by the International Commission on Radiation Units and Measurements (ICRU) and endorsed by International Standards Organisation (ISO) standards.

The operational quantities provide an appropriate and conservative estimate of the radiation protection dosimetric quantities, to which they are associated on the basis of the scheme shown in the table below:

Radiation Protection quantity	Individual monitoring	Area monitoring
Effective dose.	Hp (10)	H*(10)
Equivalent dose for the skin.	Hp (0.07)	H'(0.07.Ω)
Equivalent dose for the eye lens.	Hp (3)	H'(3.Ω)

The definitions of those terms and concepts used in the definitions of the operational quantities are presented below:

− Dose equivalent, H: is the product of the absorbed dose at a point in a tissue (D) and the quality factor (Q) for the specific radiation at that point:

$$H = D.\,Q$$

The unit for the dose equivalent is the joule per kilogram (J/kg), and is given the special name of sievert (Sv).

− Quality factor, Q, is the factor characterising the biological effectiveness of a type of radiation, based on the ionisation density along the tracks of charged particle in tissue. Q is defined as a function of the unrestricted linear energy transfer (L) of charged particles in water:

Table I-3. Quality factor (Q)

Linear energy transfer in water (keV/µm)	Q(L)
< 10	1
10/100	0.32L - 2.2
>100	300/L1/2

In the definition of equivalent dose, Q has been superseded by the radiation weighting factor (w_R), but continues being used in calculating the operational quantities used in monitoring and dosimetry.

− Linear energy transfer, L: is the average linear rate of energy loss of a charged particle in a medium, i.e., the radiation energy lost per unit length or path through a medium. It is defined

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as the quotient of dE and dl, where dE is the mean energy lost by a charged particle owing to collisions with electrons in traversing a distance dl in matter:

$$L = \frac{dE}{dl}$$

The unit for linear energy transfer is the joule per metre (J/m), but it is usually expressed in keV/µm.

− Expanded field: a hypothetical radiation field in which the fluence, and its angular and energy distribution have the same values throughout the volume of interest as at the point of reference in the actual radiation field.

− Aligned and expanded field: is an expanded field in which its fluence is unidirectional.

− ICRU sphere: is the reference phantom used by the International Commission on Radiation Units and Measurements for the definition of operational quantities used for the assessment of doses from external exposure. It consists of a 30 cm diameter sphere of tissue-equivalent material with a density of $1_{g/cm3}$ and a mass composition of 76.2 % oxygen, 11.1 % carbon, 10.1 % hydrogen and 2.6 % nitrogen.

− fluence , Φ: is the quotient of dN and da, where dN is the number of particles incident upon a sphere of cross-sectional area da:

$$\Phi = \frac{dN}{da}$$

4. Effective dose coefficients for external exposure.

They shall be established and updated by the Nuclear Safety Council, taking into account the recommendations of the International Commission on Radiological Protection publications 116 and 144 and publications updating the criteria and tables contained in these publications.

These coefficients will be published on the website of the Nuclear Safety Council.

ANNEX II

Justification of new classes or types of practices in relation to consumer products

1. Any undertaking intending to manufacture or import a consumer product for which the intended use constitutes a new class or type of practice shall provide the Directorate General for Energy Policy and Mines with all relevant information concerning:

a) The intended use of the product.

b) The technical characteristics of the product.

c) In the case of products containing radioactive substances, information on their means of fixation.

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

e) expected doses to regular users of the product.

f) Labelling and user documentation to accompany the product.

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2. The Directorate General for Energy Policy and Mines shall examine this information and assess in particular whether:

a) The performance of the product justifies its use.
b) The design is adequate to minimise exposures in normal use and the likelihood and consequences of misuse or accidental exposures or whether there should be conditions imposed with regard to the technical and physical characteristics of the consumer product.
c) the product is adequately designed to meet the exemption criteria established in the Regulation on nuclear and radioactive facilities, approved by Royal Decree 1836/1999, of 3 December, and, where applicable, is of an approved type and does not require specific precautions for its disposal when no longer in use.
d) the product is appropriately labelled and suitable documentation is provided to the user, with instructions for proper use and disposal.

ANNEX III

Dose estimation for internal exposure

1. Unless otherwise provided, throughout this Royal Decree the dose limits shall apply to the sum of the doses resulting from external exposure in a specified period, and the corresponding fifty-year committed doses (up to the age of seventy years for children) resulting from intakes occurring in the same period.

In general, the effective dose E to which an individual in age group g would have been exposed shall be determined according to the following formula:

$$E = E_{externa} + \sum_{j} h(g)_{j.ing} J_{j.ing} + \sum_{j} h(g)_{j.inh} J_{j.inh}$$

Where E_{xterna} is the effective dose from external exposure; $h(g)_{j.ing}$ and $h(g)_{j.inh}$ represent the committed effective dose per unit intake per unit of intake per radionuclide j (Sv/Bq) ingested or inhaled by an individual of theage group g; $J_{j.ing}$ and $J_{j.inh}$ represent, respectively, the corresponding intake per
ingestion or inhalation of radionuclide j(Bq).

2. Effective dose coefficients for internal exposure.

They shall be established and updated by the Nuclear Safety Council, taking into account the internal dose coefficients established by the International Commission on Radiological Protection on the basis of the basic recommendations of Publication 103 and the publications of that Commission in which the reference phantoms specified in those recommendations are developed or, in the absence of such coefficients, the dose coefficients of Publication 119 of the International Commission on Radiological Protection.

These coefficients will be published on the website of the Nuclear Safety Council.

ANNEX IV

Signposting of working areas

1. The signposting of controlled and supervised areas shall be carried out on the basis of the provisions of UNE 73302:2018, Ionising radiation symbols, or subsequent update, and in accordance with the specifications of this Annex.

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1. The risk of exposure shall be signposted using its international symbol, a "trefoil" framed by a rectangular border of the same colour as the symbol and of the same width as the diameter of the inner circumference of the symbol.

2. Controlled areas: in controlled areas, the trefoil shall be green on a white background.

a) Areas of limited stay: in these areas, the trefoil shall be yellow on a white background.

b) Areas of Regulated stay in these areas, the trefoil shall be orange on a white background.

c) Areas of Prohibited access: in these areas, the trefoil shall be red on a white background.

3. Supervised areas: in supervised areas the trefoil shall be blue-grey on a white background.

4. If in any area, there is only a risk of external exposure, the general trefoil of the area bordered with radial spikes shall be used; if there is a risk of contamination and the risk of external exposure is disregarded, the general trefoil of the area in a dotted background shall be used; and if there is both a risk of contamination and a risk of external exposure, the general trefoil of the area bordered with radial spikes in a dotted background shall be used.

5. All signs for controlled, limited stay, , regulated stay, prohibited access, and supervised areas shall be prominently displayed at the entrance and at significant locations within these areas.

6. For all types of areas, the above signs shall be complemented at the top by a legend indicating the type of area, and at the bottom by a legend indicating the type of risk.

7. Where the boundaries of an area must be temporarily signposted, fences, hinged metal bars or barrier stands with ropes, chains, tapes, etc shall be placed in the colour according to the area concerned.

8. At access points between adjacent areas of different types, the corresponding boundaries may be marked on the floor by clearly visible lines in the colours that corresponds to the areas concerned. Such signage may be supplemented by lighting in a colour appropriate to the areas concerned.

9. Within controlled and supervised areas, radioactive sources and radiation-generating equipment shall be marked with the basic symbol set out in standard UNE 73302:2018, ionising radiation symbols, or subsequent update

ANNEX V

Types of existing exposure situations

1. Exposure due to contamination of areas by residual radioactive material from:

a) Past activities that were never subject to regulatory control or were not regulated in accordance with the requirements set out in this regulation;

b) a nuclear or radiological emergency, after the emergency exposure situation has been declared ended, as provided for in the emergency management system;

c) residues from past activities for which the company undertaking is no longer legally accountable.

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2. Exposure to natural radiation sources, including:

a) Indoor exposure to radon and thoron, e.g. in workplaces, dwellings homes and other buildings;
b) External exposure to radiation from building materials.

3. Exposure to commodities excluding food, animal feed and drinking water, which incorporating:

a) Radionuclides from contaminated areas specified in paragraph 1; or
b) Naturally occurring radionuclides.

ANNEX VI

Indicative list of types of building materials to be taken into account in relation to emitted gamma radiation referred to in Article 80

1. Building materials or natural additives of igneous origin or which may be associated with uranium mineralisation, e.g. granitoids (such as granite, syenite and orthogneiss), porphyries, tuff, pozzolana (pozzolanic ash), lava or aluminous schist alum-shale.
2. Building materials incorporating naturally occurring radioactive material such as fly ash, phosphogypsum or phosphate sludge, slag from phosphorus, tin or copper production, red mud, etc.

Annex VII

Activity concentration index for gamma radiation emitted by building materials

The activity concentration index I_C and I_D referred to in Article 80 are given by the following formulas:

$$I_C = C_{Ra\text{-}226}/300 + C_{Th\text{-}232}/200 + C_{K\text{-}40}/3000$$

$$I_D = [(281+16.3\ \rho d - 0.0161\ (\rho d)_2) \cdot C_{Ra\text{-}226} + (319+18.5\ \rho d - 0.0178\ (\rho d)_2) \cdot C_{Th\text{-}232} + (22.3 +1.28\ \rho d - 0.0014\ (\rho d)_2) \cdot C_{K\text{-}40}] \cdot 10_{-6} + 0.19$$

Where $C_{Ra\text{-}226}$, $C_{Th\text{-}232}$ and $C_{K\text{-}40}$ are the activity concentrations of Ra-226, Th-232 and K-40 expressed in Bq/kg, ρ the density expressed in $_{kg/m3}$ and d the thickness of the material expressed in m, and referenced to the building material according to its intended use.

ANNEX VIII

List of aspects to be considered for the preparation of the national action plan to address the long-term risks arising from of radon exposures

1. Strategy to conduct surveys of indoor radon concentrations or soil gas concentrations in the field, 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 in rock or soil).

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2. The approach, data and criteria used for the delimitation 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 the types of workplaces and buildings with public access, such as schools, underground workplaces or those located in certain areas, where measures are required on the basis of a risk assessment, taking into account, for example, 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), both for existing and for new buildings.

5. Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and resources for implementation of the action plan.

6. Strategy to reduce radon exposure in dwellings and for giving priority to addressing the situations identified in paragraph 2.

7. Strategies to facilitate the implementation of post-construction remedial actions.

8. Strategy, including methods and tools, to prevent the ingress of radon into newly constructed buildings, including the identification of those building materials with significant radon exhalation.

9. Scheduling for reviews of the action plan reviews.

10. Strategy for communication to increase public awareness and inform local decision-makers, employers and workers employees of about the risks of radon, including in relation to smoking.

11. Guidance on measurement methods and techniques tools for measurements and implementation of remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.

12. If appropriate, provision of financial support for radon measurement campaigns and for the implementation of 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 relevant corresponding programmes, such as programmes on energy efficiency saving and indoor air quality programmes.

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