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Royal Decree 413/1997, of March 21st, on the operational protection of off-site workers running the risk of exposure to ionising radiations due to their interventions in the controlled zone

The objective of Royal Decree 53/1992, of January 24th, which approves the Regulation on protection against ionising radiations, is to establish the basic radiological protection standards to prevent non-stochastic biological effects and eliminate the probability of stochastic biological effects appearing, to values considered acceptable for professionally exposed workers and members of the public as a result of activities implying a risk of exposure to ionising radiations.

In view of the scope of application of the aforementioned provision, and of the contents of Directives 80/836/EURATOM and 84/467/EURATOM, there is a clear need to contemplate specifically the regulation of the radiological protection of those workers known as “off-site” workers that are required to intervene in the controlled zone.

As a result, Directive 90/641/EURATOM relating to the operational protection of off-site workers running the risk of exposure to ionising radiations due to their intervening in the controlled zone is adopted.

This Royal Decree is drawn up with the objective of transposing the aforementioned standard to the Spanish legislation, thus completing the system for the protection of all persons intervening in the controlled zone of nuclear or radioactive facilities, the said Decree being issued pursuant to the stipulations of articles 149.1.7.^a and 16.^a of the Constitution.

By virtue of the above, and in response to proposals by the Ministries of Economy and the Exchequer, Labour and Social Affairs, Industry and Energy and Public Health and Consumption, and in view of the favourable report issued by the Nuclear Safety Council, in accordance with the State Council and following deliberation by

the Cabinet during its meeting of March 21st 1997,

I HEREBY PROVIDE AS FOLLOWS:

Article 1. Objective and field of application

The objective of the present Royal Decree is to ensure the operational radiological protection of off-site workers, as defined in article 2, running the risk of exposure to ionising radiations due to their intervening in the controlled zone, in enactment of the Nuclear Energy Act, Law 25/1964, of April 29th, and complementing the provisions of Royal Decree 53/1992, of January 24th, approving the Regulation on Protection against Ionising Radiations (RPIR).

Article 2. Definitions

For the purposes of the present Royal Decree, the terms listed below shall have the following definitions:

- a) Controlled zone: place of work classified as such on the basis of the risk of exposure to ionising radiations, in accordance with article 21 of the RPIR).
- b) Off-site worker: any worker classified as being professionally exposed, in accordance with the provisions of section c) appendix 1 of the RPIR, that intervenes in any manner in the controlled zone of a nuclear or radioactive facility and who is employed temporarily or permanently by an external company, including workers undergoing professional practical periods, apprentices or students, or who renders his services as a self-employed worker.
- c) Licensee of the facility: any physical or legal person that, in accordance with the Nuclear Energy Act, Law 25/1964, of April 29th, and the regulations for its enactment, operates a nuclear or radioactive facility and is subject to a procedure of declaration or authorisation for performance of his activities.
- d) External company: any physical or legal person, other than the licensee of the facility, that is required to carry out an installation of any type in a controlled zone at a nuclear or radioactive facility.

e) Intervention of a worker: set of activities carried out by an off-site worker in the controlled zone of a nuclear or radioactive facility.

f) Radiological surveillance system: set of measures aimed at applying the corresponding provisions of the RPIR, in particular those contained in Title III, as they affect off-site workers.

g) Individual radiological surveillance document: instrument for the recording of data, including the appropriate aspects relating to the worker, arising from application of the radiological surveillance system.

Article 3. Procedure for declaration of activities to be performed by external companies

1. External companies are required to submit the corresponding declaration and to be included on a register set up for this purpose at the Nuclear Safety Council, known as the Register of External Companies. The following data should be provided:

- a) Identification of the company.
- b) Company name
- c) Tax identification code.
- d) Activity performed.
- e) Legal declaration accrediting the availability of the necessary technical and human resources, which may be in-house or contracted, and sufficient know-how to comply with the requirements of the present standard, to the extent applicable.

Any modification to the initial data should be documented and submitted to the Register of External Companies.

2. The Nuclear Safety Council may carry out the controls and inspections that it deems to be necessary with respect to external companies, with a view to verifying the authenticity of the data in the

Register and the degree of compliance with the obligations established in this provision.

Article 4. Obligations of the external company

The external company shall be responsible for the radiological protection of its workers, in application of what is established in the RPIR, and in particular should:

a) Adhere to and ensure adherence to the basic principles and standards of protection established in articles 4 to 11 of the RPIR, and in particular to the dose limits.

b) Provide its workers with information and training in relation to the radiological protection demanded in performance of their work, in accordance with article 18 of the RPIR.

c) Control the doses received by its workers in the performance of their work, maintaining the corresponding dosimetry archives in accordance with articles 30 to 39 of the RPIR and registering the doses assigned by the official dosimetry system in the individual radiological surveillance document.

d) Maintain medical surveillance of its workers in accordance with articles 40 to 46 of the RPIR.

e) Request from the Nuclear Safety Council and assign to each worker the individual radiological surveillance document and guarantee that this document is continuously updated for the appropriate purposes.

Article 5. Obligations of the licensee of the facility

1. The licensee of the facility in whose controlled zone there is an intervention by off-site workers shall be responsible, within the realm of his activity and competence, for the operational aspects of the radiological protection of his workers, guaranteeing that they adhere to the basic principles, protection standards and dose limits established in articles 4 to 11 of the RPIR and further developed in the official documents of the facility.

2. The licensee of the facility shall:

A) *Prior to initiation of the intervention:*

a) Ensure that the company is included on the Register of External Companies.

b) Ensure that the worker is recognised as being medically suitable for the intervention to be assigned to him.

c) Ensure that the worker has received the basic training on radiological protection referred to in article 4, paragraph b) of the present Royal Decree.

d) Provide specific information and training in relation to the specific characteristics of both the controlled zone and the intervention.

e) Ensure that the worker is subjected to an official individual dosimetry control of his exposure, adequate for the characteristics of the intervention.

f) Ensure that the dosimetry data are complete and check that the dosimetric conditions of the worker are suitable for the nature of the intervention.

In the absence of data referring to the official dosimetry, these conditions may be assessed on the basis of data from the operational dosimetry, which shall remain valid for a maximum period of ninety days.

B) *In each intervention:* ensure that the worker in question has available the necessary individual protection equipment, supplying where appropriate the specific material to be used in each working area of the controlled zone.

C) *Subsequent to completion of the intervention:* register in the individual radiological surveillance document data referring to the installation, the period of the intervention, the operational dose estimated as a result of whatever operational dosimetric tracking might have been necessary and the internal dose determined by the technical services

reporting to the licensee, as detailed below in article 7.

Article 6. Obligations of off-site workers

All off-site workers are obliged to collaborate with those responsible for radiological protection, both those of their own company and those of the licensee of the facility, in their protection against ionising radiations, fulfilling the standards established by them.

Article 7. Individual radiological surveillance document

1. The individual radiological surveillance document is a public, personal and non-transferable document.

2. The individual radiological surveillance document and its identification number shall be issued by the Nuclear Safety Council. This number shall be maintained in successive renewals of the document.

3. The individual radiological surveillance document shall include the following:

A) *On assignment of the document:*

a) Data relating to the identity of the worker, including gender and date of birth.

b) Previous dosimetry data of the worker.

c) Name, address, date of entry and registration number of the company to which the worker belongs at each moment.

B) *Prior to initiating an intervention:*

a) Medical classification of the worker, in accordance with what is established in the Regulation on Protection against Ionising Radiations.

b) Date of the last medical check-up.

c) Updated dosimetry data of the worker.

d) Data on the basic training of the worker on radiological protection.

C) *Data to be included on completion of an intervention:*

a) Identification of the installation.

- b) Period covered by the intervention.
- c) Dose assigned provisionally by the operational dosimetry system.
- d) Monthly dose assigned by the official dosimetry system. In the event of non-uniform exposure, the dose shall be assigned to the corresponding organs or tissues.
- e) Activity incorporated and committed dose if the work may have implied the risk of internal contamination.
- f) Effective equivalent dose.

4. The Nuclear Safety Council shall have the power to establish the format and content of this document and to modify it in relevant circumstances.

Article 8. Infringements and penalties

Without prejudice to whatever civil, penal or other liabilities might be incurred, the events that constitute infringement of the provisions of this Royal Decree shall be penalised by the authority competent in each case, in accordance with what is established in chapter XIV of the Nuclear Energy Act, Law 25/1964, of April 29th, in the wording given to it by the sixth additional provision of Law 40/1994, of December 30th, on the Ordering of the National Electricity System, in article 2, paragraph d) and the second additional provision of Law 15/1980, of April 22nd, creating the Nuclear safety Council, and articles 32 and following articles of the General Health Act, Law 14/1986, of April 25th, as well as in accordance with the catalogue of infringements and penalties established in article 64 of Royal Decree 53/1992, of January 24th, approving the Regulation on Protection against Ionising Radiations.

First transitory provision. Entry on the Register.

External companies are obliged to apply for inclusion on the Register of External Companies established in article 3 within

six months as of the official creation of this Register.

Second transitory provision. Radiological licences.

Until such time as the format of the individual radiological surveillance document is defined, the current radiological licences shall be used, any precept of the said licences that contradicts what is established in the present Royal Decree being left null and void.

First final provision. Enactment and application.

The competent Ministers are empowered to dictate the provisions required for the enactment of the present Royal Decree and for its compliance.

Second final provision. Entry into force.

The present royal decree shall enter into force on the day following its publication in the "Official State Gazette".

Given in Madrid on March 21st 1997.

JUAN CARLOS REX.

The Deputy Vice-President of the Government and Minister attached to the Presidency

FRANCISCO ÁLVAREZ-CASCOS FERNÁNDEZ