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CSN

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Spanish Nuclear Safety Council (CSN) Instruction IS-08, of the 27th July 2005, on the criteria applied by CSN to request specific advise on radiation protection from the owners of the Nuclear and Radioactive Facilities

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Article 2 a) of the Act 15/1980, dated 22 April, on the Creation of the Spanish Nuclear Safety Council, as amended by the 1st Additional Provision to the Act 14/1999, dated 4 May, on the Prices and Fees for Public Services Rendered by the Nuclear Safety Council, grants this public body the authority 'to develop and approve all required Instructions, Circular Letters, and Technical Guides with regard to nuclear and radioactive facilities and to any activities relating to nuclear safety and radiation protection'.

On the other hand, Royal Decree 783/2001, dated 6 July, approving the Regulation on Health Protection against Ionising Radiation, sets forth that the Nuclear Safety Council, in consideration of radiation risk, may require the operators of activities under Article 2 of the abovementioned Regulation either to have an in-house Radiation Protection Service or to contract a Radiation Protection Technical Unit in order to obtain specific advice on radiation protection and to entrust all specific functions on this matter to them.

Radiation Protection Services and Technical Units, which shall be duly authorised by the Nuclear Safety Council, shall consist of a Head and a team of technical experts in radiation protection.

Radiation Protection Services shall be organised and shall operate separately from other functional units. The Head of this Service shall report directly to the facility licensee or, where applicable, to person holding the highest responsibility within the facility or centre. This shall be without prejudice to the necessary coordination with the prevention services established by Labour Law.

The Nuclear Safety Council has usually required the facility licensee to create their own Radiation Protection Services according to the particular risks and complexity associated with each facility.

In order to facilitate the creation of the necessary documentation to apply for the authorisation of a Radiation Protection Service, in 1987 the Nuclear Safety Council approved the Safety and Security Guide GS-7.3, 'Bases for Establishment pf services or technical units fo Protection against Ionising Radiations' (first amendment thereof is dated 1998).

The approval of this Instruction responds to the need to regulate the criteria applied by the Nuclear Safety Council to require specific advice on radiation protection in nuclear and radioactive facilities.

By virtue of the foregoing, in accordance with the legal authorisation provided by Article 2, Parts a) and j) of the Act 15/1980, dated 22 April, on the creation of the Spanish Nuclear Safety Council, as amended by the 1st Additional Provision to the Act 14/1999, dated 4 May, in consultation with all affected sectors, and after receiving all appropriate technical reports, this Nuclear Safety Council, in its meeting on 27 July 2005, has agreed upon the following provisions:

One. Objective and Scope of Application

The objective of this Instruction is defining the criteria to be applied by the Nuclear Safety Council for requiring the operators of nuclear and radioactive facilities to obtain specific advice on radiation protection, either by establishing and allocating resources to an in-house Radiation Protection Service or by outsourcing the services of a Radiation Protection Technical Unit.

The scope of application of this Instruction shall be that of nuclear and radioactive facilities

For the purposes of this Instruction, facilities are classified in three groups:

1. Nuclear and radioactive fuel-cycle facilities

2. Radioactive facilities in health centres

3. Other radioactive facilities (research, industrial, etc.)

Two. Definitions

Certificate of Head for Radiation Protection: Document issued by CSN, indispensable to become the Head of a Radiation Protection Service or Technical Unit, in accordance with CSN Instruction IS-03, dated 6 November 2002, on the Qualifications Required to Become a Certified Expert in Protection against Ionising Radiation.

Radiation Protection Service or Technical Unit Head: An individual that, having specific qualifications, training and experience in radiation protection, also holds a Certificate of Head for Radiation Protection granted by CSN in accordance with the provisions of CSN Instruction IS-03, dated 6 November 2002, on the Qualifications Required to Become a Certified Expert in Protection against Ionising Radiation.

Radiation Protection Service: A body expressly authorised by the Nuclear Safety Council to perform the functions set forth in the Regulations on Health Protection against the Dangers of Ionising Radiation as a part of a nuclear or radioactive installation owned by one or various operators.

Technical Expert in Radiation Protection: An individual that, having specific qualifications, training and experience in radiation protection, must also hold a certification issued by the Head of a Radiation Protection Service or Technical Unit, in accordance with the

provisions of CSN Instruction IS-03,of the 6th November 2002, on the Qualifications Required to obtain recognition as an expert in Protection against Ionising Radiation.

Radiation Protection Technical Unit: A body expressly authorised by the Nuclear Safety Council to perform the functions set forth in the Regulations on Health Protection against Ionising Radiation as an external service contracted by the licensee of a nuclear or radioactive facilitiy

The definitions of the remaining terms and concepts used in this Instruction shall correspond to those set forth by the legislation below:

Act 25/1964, dated 29 April, on Nuclear Energy (Official State Gazette No. 107, dated 4 May), as amended by Act 54/1997, dated 27 November, on the Power Sector (Official State Gazette No. 285, dated 28 November).

Act 15/1980, dated 22 April, on the Creation of the Spanish Nuclear Safety Council (Official State Gazette No. 100), as amended by Act 14/1999, dated 4 May, on the Prices and Fees for Public Services Rendered by the Nuclear Safety Council (Official State Gazette No. 107, dated 5 May).

Royal Decree 1836/1999, dated 3 December, approving the Regulations on Nuclear and Radioactive Facilities (Official State Gazette No. 313, dated 31 December).

Royal Decree 783/2001, dated 6 July, approving the Regulation on Health Protection against Ionising Radiation (Official State Gazette No. 178, dated 26 July).

Royal Decree 1891/1991, dated 30 December, on the Installation and Utilisation of X-ray Equipment for Medical Diagnosis Purposes (Official State Gazette No. 3, dated 3 January 1992).

Royal Decree 1976/1999, dated 23 December, on the Quality Standards in Radiodiagnostic (Official State Gazette No. 311, dated 29 December).

Royal Decree 1841/1997, dated 5 December, on the Quality Standards in Nuclear Medicine (Official State Gazette No. 303, dated 19 December).

Royal Decree 1566/1998, dated 17 July, on the Quality Standards in Radiotherapy (Official State Gazette No. 206, dated 28 August).

Royal Decree 220/1997, dated 14 February, Creating and Regulating the Official Certificate of Specialist in Hospital Radiophysics (Official State Gazette No. 52, dated 1 March).

Royal Decree 413/1997, dated 21 March, on the Operational Protection of Outside exposed Workers to the Risk of Ionising Radiation during their Activities in Controlled Areas (Official State Gazette No. 91, dated 16 April).

Nuclear Safety Council Instruction IS-03, of the 6th November 2002, on the Qualifications Required to obtain recognition as an expert on Protection against Ionising Radiation (Official State Gazette No. 297, dated 12 December).

Three. Criteria Applied by the Nuclear Safety Council to Require the Operator of a Facility to Obtain Specific Advice on Radiation Protection

1. Nuclear and radioactive fuel-cycle facilities

All nuclear and radioactive fuel-cycle facilities shall have an in-site Radiation Protection Service.

The necessity for a Radiation Protection Service during the inactive phases of the dismantling process (latency time) will be determined by CSN on a case-by-case basis, given the radiological implications of the procedures carried out during such phases.

The reason for this requirement is that nuclear and radioactive fuel-cycle facilities are immensely complex in terms of radiation protection during all their phases of development, from start-up to dismantling operations. The intervening factors are as follows:

• The number of exposed workers, both permanent staff and contract workers, carrying out their labour duties in such facilities is usually high.

• Some of such workers perform their activities in areas with high levels of radiation and contamination, where significant doses may be recorded.

• Different types of radiation (alpha, beta, gamma, neutron) and risks (external irradiation, external contamination, internal contamination) might be found in such facilities, and this requires the implementation of sophisticated radiological and dosimetric monitoring techniques.

• Radiation dose in such facilities is determined by a large variety of elements (engineering, chemical, maintenance, etc.), and this requires an integrated management of radiation protection where different departments of the installations become involved.

2. Radioactive facilities in health centres

a) All health centres operating simultaneously with radiotherapy, nuclear medicine, and radiodiagnostic facilities shall have an in-site Radiation Protection Service.

b) Health centres with the following types of radioactive facilities shall obtain specific advice on radiation protection from a Radiation Protection Service or Technical Unit:

I. Facilities with cyclotrons for the production and medical use of short-lived radionuclides, since they generate high activities, the emission energies from the isotopes produced by them are high, and they involve the synthesis of radiopharmaceuticals.

II. X-ray facilities for medical diagnostic, since, according to Royal Decree 1891/1991 on the Installation and Utilisation of X-ray Equipment for Medical Diagnostic Purposes, such facilities shall be declared by submitting a certification of the project issued by a Radiation Protection Service or Technical Unit and shall be inspected annually by means of a quality control performed by a Radiation Protection Service or Technical Unit.

As far as other health centres are concerned, CSN shall evaluate the need for specific advice on radiation protection on a case-by-case basis.

3. Other radioactive facilities (research, industrial, etc.)

There is a vast range of applications of ionising radiation in different fields of industry, research, teaching, and commerce.

The main purpose for which the Nuclear Safety Council requires these facilities to have a Radiation Protection Service or Technical Unit is the achievement of an integrated management of all matters on radiation protection.

a) Large-scale radioactive research and teaching facilities, with over 50 people using radioactive materials and over 10 different sites where radioactive isotopes are handled, shall have an in-site Radiation Protection Service.

b) As far as the following facilities are concerned, the need for specific advice on radiation protection, either by creating an in-site Radiation Protection Service or by contracting an external Radiation Protection Technical Unit, will be determined by CSN on a case-by-case basis, upon assessment of the level of associated risk:

I. Facilities for the production and marketing of radioactive isotopes

II. Industrial gammagraphy and radiology facilities

III. Industrial irradiation facilities

IV. Other

Four. Deadlines for Implementation

1. Nuclear and radioactive fuel-cycle facilities

In-site Radiation Protection Services shall be fully functional at the beginning of the operational phase of these facilities.

Radiation Protection Services shall remain functional both during the operational phase of the facilities and during the active phase of their dismantling process.

2 & 3. Radioactive facilities in health, research, industrial centres

Notwithstanding the provisions on medical radiodiagnostic facilities of RD 1891/1991, dated 30 December, on the Installation and Utilisation of X-ray Equipment for Medical Diagnostic Purposes, once CSN has submitted the requirement for creating an in-site Radiation Protection Service, the facility operators shall provide this service with personnel, technical, and documentary resources and shall apply for the corresponding authorisation from the Nuclear Safety Council no latter than one year as of the date of the requirement. CSN should determine that the facility requires external advice on radiation protection, the facility operators shall contract a Radiation Protection Technical Unit within a maximum period of three months.

Five. Infractions and Sanctions

Without prejudice to the civil, penal or other responsibilities that may be incurred, the failure to comply with the provisions of this Instruction, shall be sanctions according to what is established in Chapter XIV of Law 25/1964, of 29th April, on Nuclear Energy, according to the wording given by the Fifth Additional Provision of Law 54/1997, of 27th November, on the Electricity Sector, as well as by the Fifth Additional Provision of the Law 14/1999, of 4th May, on Public Prices and Fees for services rendered by the Nuclear Safety Council, and in accordance with the provisions of Article 69 of Royal Decree 783/2001, of 6th July, approving the Regulations on Health Protection against Ionising Radiation (Official State Gazette No. 178).

Single Transitory Provision

This Instruction shall not affect any Radiation Protection Services authorised prior to its publication.

Single Repeal Provision

Any provision of equal or inferior rank that is contrary to this present Instruction shall be repealed.

Single Final Provision. Entry in Force.

This present Instruction shall enter in force on the day following its publication in the Spanish Official Gazette.

This I communicate to you for your knowledge and pertinent effects

In Madrid, on this 27th July 2005

Signed by the President,
Mrs. María-Teresa Estevan Bolea