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7563 *Nuclear Safety Council Instruction IS-39, of June 10th 2015, regarding control and monitoring in the manufacturing of packages for the transport of radioactive material.*

Article 2.a) of Law 15/1980, of April 22nd, creating the Nuclear Safety Council (CSN), empowers this public body to «draw up and approve technical instructions, circulars and guidelines relating to nuclear and radioactive facilities and activities relating to nuclear safety and radiological protection ».

Article 77 of Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radioactive Facilities, establishes that the Directorate General for Energy (now the Directorate General for Energy Policy and Mines) shall be responsible for the approval or validation of transport package models and the authorisation of shipments of radioactive material required by the specific regulations, following a mandatory and binding report by the CSN.

Furthermore, the transport of radioactive material is subject to the requirements set out in Royal Decree 783/2001, of July 6th, approving the Regulation on the Protection of Health against Ionising Radiations, the aim being to establish standards relating to the protection of the workers and members of the public against the risks resulting from ionising radiations.

The approval requirements to be met by radioactive material transport packages are those defined in the different international regulations on the transport of dangerous goods applicable in Spain, such as the following, which are listed along with the provisions for their inclusion in national law:

European agreement concerning the international carriage of dangerous goods by road (ADR), compliance with which is referred to by Royal Decree 97/2014, of February 14th, regulating shipments of dangerous goods by road in the Spanish territory.

Regulation concerning the international carriage of dangerous goods by rail, compliance with which is referred to by Royal Decree 412/2001, of April 20th, regulating different aspects of the transport of dangerous goods by rail.

International Civil Aviation Organisation (ICAO) technical instructions for the safe transport of dangerous good by air, compliance with which is referred to by Royal Decree 1749/1984, of August 1st, on the transport without Risk of Dangerous Goods by air and technical instructions.

International Maritime Organisation (IMO) code on the international transport of dangerous goods by sea.

The safe transport of radioactive material is guaranteed fundamentally by the transport package, that is to say by an adequate package design, by establishing limits regarding the content of the radioactive material to be transported and by the processes defined for the loading of this material in the packaging. Consequently, it is important to establish a control ensuring that the packages are manufactured in accordance with the original design analysed.

Royal Decree 97/2014, of February 14th, regulating the transport by road of dangerous goods in the Spanish territory and replacing and annulling Royal Decree 551/2006, which previously regulated such activities, includes an important revision of the provisions governing the process of controlling the manufacturers of packaging used for the transport of dangerous goods.

Thus, Royal Decree 97/2014 repeals the Ministerial Order of March 17th 1986 on standards for the homologation of containers and packaging for use in the transport of dangerous goods and becomes part of its provisions, among them those relating to processes for the homologation and control of the manufacturing of containers and packaging.

As regards these processes, Royal Decree 97/2014 includes a special consideration for radioactive material transport packages. Thus, the second section of article 8 of chapter III leaves the control of the manufacturing of such packages subject to approval within the same realm of competence as approval of the package design, i.e. the Directorate General for Energy Policy and Mines (DGPEM), establishing that compliance regarding production shall be determined in accordance with the provisions set out by the DGPEM for approval of the package design, which requires a mandatory report by the CSN.

However, Royal Decree 97/2014 does not set out any procedure for the control of compliance regarding production in the case of radioactive material packages subject to design approval, although it does establish that the checks involved in this process shall be carried out by the Control Organisations (CO) legally established in accordance with its article 12. In this respect it is also important to bear in mind that, pursuant to article 2.c) of Law 15/1980, of April 22nd, and apart from the checks performed by the CO's, the CSN may carry out inspections in relation to radioactive material shipments and the approval of radioactive material packages, in order to guarantee compliance with the legislation in force.

The first objective of the present Instruction is, therefore, to set out the procedure to be adhered to establish compliance in production in the specific case of receptacles and packaging and large bulk containers (GRG/IBC) and large packages (in the Instruction these will all be encompassed within the term «packaging») used for the transport of radioactive material and with package design approval.

Consequently, the Instruction will affect the manufacturing of packaging that, in accordance with the regulations on the transport of dangerous goods in force at the time of publication of this Instruction, require package design approval: type B(U) packages, type B(M) packages and type C packages; packages for the transport of fissile materials and packages containing more than 0.1 kg of uranium hexafluoride.

On the other hand, Royal Decree 97/2014 defines only the process for the control of the manufacturers of package types subject to approval but not of those types of packaging for which the regulations on the transport of dangerous materials do not require such approval: excepted, industrial and type A packages. Nevertheless, in view of the importance of package design for safety in transport, the CSN considers it necessary for there to also be a system for the control of the manufacturing of this type of packages, graded in keeping with the lower risk it entails.

For this type of package there is no certificate of approval issued by the competent authority, and it is sufficient for the consignor to provide the said authority with documentation demonstrating that the design of the package meets the requirements of the regulation on the transport of dangerous substances, if so requested. However, this regulation does not specify the nature of this documentation on compliance, as a result of which there is no clear reference allowing for the subsequent control of package manufacturing. For this reason, this Instruction aims to indicate the aspects that are to be taken into account in the development of this documentation and to define its generic structure.

Consequently, the second objective of this Instruction is to define the procedure to be used to determine production compliance in the case of packages used for the transport of radioactive material and not requiring package design approval and to specify the minimum contents of the documentation that will demonstrate that the design of the package meets the regulatory requirements and serve as a reference to check production compliance in the manufacturing of packaging.

The procedure for the control of production compliance for the manufacturing of packages not subject to design approval is adapted in the Instruction to the lowest level of risk of the radioactive material that they can transport, with respect to packages subject to approval, allowing for the alternative of production compliance being determined by the purchaser of the packaging or of the latter using a CO.

Pursuant to all the above, and in compliance with the legal entitlement contemplated in article 2, section a) of Law 15/1980, of April 22nd, creating the Nuclear Safety Council, and following consultations with the affected sectors and issuing of the appropriate technical reports, this Council agreed as follows during its meeting held on June 10th 2015:

One. Objective and scope of application.

1. The objective of the present Instruction is to identify the procedure to be adhered to control the manufacturing in Spain of receptacle and packaging and large bulk containers (GRG/IBC) and large packages (hereinafter «packaging») used for the transport of radioactive material, through the control of compliance in production, such that:

a. In the case of packages requiring design approval, as established in the regulation on the transport of dangerous goods, there is assurance that the packaging is manufactured in accordance with the documentation on which such approval is based.

b. In the case of packages not requiring design approval, there is assurance that the packaging is manufactured in accordance with the documentation demonstrating compliance with the requirements set out in the regulation on the transport of dangerous goods; in this respect the minimum structure that this documentation must have is indicated and the consignor is required to make it available to the competent authority, in accordance with the requirements of the said regulation.

2. The present Instruction is applicable to the manufacturers and purchasers of packaging and to the consignors of radioactive packages whose business address is in Spain, regardless of whether or not the packages are required to have a design approval certificate.

3. The present Instruction is also applicable to Control Organisations (CO) legally established in accordance with Royal Decree 97/2014, of February 14th, regulating the transport of dangerous goods by road in the Spanish territory, as regards the scope of the control of compliance in the production of packaging for the transport of radioactive material described in article six of this Instruction.

Two. Definitions.

The definitions of the terms and concepts contained in the present Instruction correspond to those included in the following provisions:

Royal Decree 97/2014, of February 14th, regulating the transport of dangerous goods by road in the Spanish territory.

European agreement concerning the international carriage of dangerous goods by road (ADR).

Regulation concerning the international carriage of dangerous goods by rail (RID).

International Civil Aviation Organisation (ICAO) technical instructions for the safe transport of dangerous good by air.

International Maritime Organisation (IMO) code on the international transport of dangerous goods by sea.

Furthermore, the following definitions are also applicable for the exclusive purposes of the present Instruction:

Purchaser: physical or legal person who acquires the packaging. The purchaser may or may not act as the consignor of the radioactive package finally prepared and transported.

Manufacturer: physical or legal person who manufactures the packaging that will ultimately be used to produce a radioactive package. Those who manufacture any of the elements, materials or components that will form part of the packaging are not considered to be the manufacturer of the said packaging.

Packaging: one or more containers and all other elements or materials required to allow the container to fulfil its retention function and any other safety function.

Quality Assurance Programme: Series of policies, measures and scheduled systematic actions aimed at providing assurance that the quality and degree of safety required by the standards will be achieved.

Three. Procedure to be adhered to control compliance in the production of packaging for the transport of radioactive material requiring package design approval.

1. The packaging manufacturer shall adopt all the measures required to ensure that the manufacturing process is in accordance with the corresponding package design approval certificate and the documentation on which the approval is based.

2. For each item of packaging manufactured the manufacturer shall draw up a final manufacturing dossier including at least the corresponding design specification, certificates for the materials used during manufacturing and the inspection, testing and checking certificates and records required by the documentation on which the approval is based or included in the package design approval certificate.

3. The packaging production compliance checks are the responsibility of the manufacturer and shall be performed by a legally established Control Organisation (CO), in accordance with Royal Decree 97/2014, of February 14th, for each package design.

4. The production compliance check shall be carried out in accordance with the provisions of article six of the present Instruction, taking as a reference the package design approval and the quality assurance programme applied by the packaging manufacturers, included in the management system required by the regulation on the transport of dangerous goods.

5. In the case of packaging for which the manufacturing process is continuous, the production compliance check shall be performed at least every two years.

6. If the manufacturing process is carried out intermittently or occasionally, the production compliance check will continue to be valid if it has been carried out within two years prior to the initiation of the said manufacturing process.

7. Production compliance shall be asserted by the CO through the issuing of a production compliance report, which shall be of the model included in Appendix E-5 of Annex 7 of Royal Decree 97/2014. This document shall be filed and kept in custody by the CO in accordance with the requirements of Royal Decree 97/2014 and a copy shall be provided to the manufacturer of the packaging and the Directorate General for Energy Policy and Mines of the Ministry of Industry, Energy and Tourism, which shall send a copy to the Nuclear Safety Council.

Four. Procedure to be adhered to control compliance in the production of packaging for the transport of radioactive material not requiring package design approval.

1. Pursuant to the provisions of the regulation on the transport of dangerous goods, the consignors of packages not subjected to approval must possess documentation demonstrating compliance with the applicable provisions of the said regulation (hereinafter «compliance documentation»). This documentation shall cover at least the items indicated in article five of this Instruction.

2. The packaging manufacturer shall adopt all measures required to ensure that the manufacturing process is in accordance with the corresponding compliance documentation.

3. The packaging production process checks may be carried out by the purchaser of the packaging, although the latter may also use a legally established Control Organisation (CO) in accordance with the provisions of Royal Decree 97/2014.

4. Package production compliance shall be established in accordance with the provisions of article six of the present Instruction, taking as a reference the package compliance documentation and the quality assurance programme applied by the packaging manufacturers and included in the management system required by the regulation on the transport of dangerous goods. The production compliance check shall be carried out prior to acquisition of the packages.

5. If the purchaser performs the production compliance check, the actions performed and their results shall be documented and controlled in accordance with a procedure established for this purpose.

6. If the checks are performed by the CO, the latter shall issue a product compliance certificate, which shall be of the model included in Appendix E-5 of Annex 7 of Royal Decree 97/2014. This document shall be provided to the purchaser of the packaging. If the purchaser is not the consignor, the purchaser shall provide a copy of this certificate to the consignor, who shall file it in accordance with the provisions of the following point.

7. The consignor of radioactive packages not subject to design approval shall possess documentation attesting to the performance of packaging production process checks demonstrating that manufacturing has been carried out in accordance with the corresponding compliance documentation. The consignor shall retain this documentation for at least one year after the cease of the use of the packaging and shall keep it available for submittal to the Nuclear Safety Council.

Five. *Contents of documentation demonstrating compliance with the regulation on the transport of packages not subject to design approval.*

1. The compliance documentation may be issued by the consignor, based on the documentation provided by the designer, the manufacturer or the supplier of the packaging, or by the designer or manufacturer.

2. The compliance documentation shall contain the information required for an analysis of the design of the package from the point of view of nuclear safety and radiological protection, demonstrating compliance with each of the applicable requirements of the regulation on the transport of dangerous goods, this information being at least the following, depending on the type of package:

a. Basic administrative information (name of package design, designer, type of package, operational restrictions and transport mode restrictions, edition of the regulations used as a reference to demonstrate compliance).

b. Specifications of acceptable contents.

c. Specifications of packaging defining its design, including drawings.

d. Package performance characteristics. This section shall describe the physical and operational characteristics of the package aimed at complying with the safety requirements defined by the standards, such as the containment, heat removal and shielding capacities.

e. List of the provisions of the standards on the transport of dangerous goods applicable to the package design.

f. Requirements for operation of the package.

g. Requirements for package maintenance and periodic verification.

h. Management system, including the quality assurance programme applied to ensure compliance with the standards.

i. Basic illustration of package.

j. Technical analyses demonstrating the fulfilment of the standards requirements, as appropriate:

i. Structural analysis

ii. Thermal analysis

iii. Containment design analysis

iv. External dose rate analysis

Six. *Scope of production compliance checks*

1. Production compliance checks shall be carried out through the performance of an audit of the packaging manufacturer and the control of production (including a sample of the packages manufactured).

a. The control of production shall preferably be carried out during manufacturing and shall be performed for each type of packaging. It shall include the following activities:

i. Inspection of the production resources and of materials to be used during manufacturing.

ii. Documentary checks and physical verifications to ensure that packaging in the manufacturing process or already manufactured are in accordance with the prototype approved or described in the compliance documentation, in the case of packages not subject to design approval. Calibrated apparatus or instruments shall be used for the control of materials and the performance of measurements.

iii. Analysis of the results of whatever inspections tests and checks the packaging or its components might have been subjected to during manufacturing.

b. The audit performed with respect to the manufacturer shall verify that the latter has implemented a quality assurance programme suitable for the manufacturing of the packages to be supplied. This audit shall preferably be carried out prior to the start of the manufacturing process and may affect the manufacturing of different types of packages. Attention shall be paid in this audit to the control of the manufacturer on the suppliers of materials and subcontractors.

2. The manufacturer shall provide the CO or the purchaser of the packaging where appropriate, with access to the manufacturing facilities and documentation required to carry out the inspections described in the previous section.

3. As regards the procedure described in article four on production compliance control for packages not requiring package design approval, and for the specific case of acquisition of the packages being carried out periodically, the scope of the checks may be reduced to that set out in section a) of point 1 of the present article only if the manufacturer is included on the purchaser's list of approved suppliers and is periodically inspected by the latter.

Seven. *Sanctions.*

The present Nuclear Safety Council Instruction is binding, in accordance with the provisions of article 2.a) of Law 15/1980, of April 22nd, creating the said Nuclear Safety Council, for which reason any case of non-compliance shall be penalised as established in Chapter XIV of the Nuclear Energy Act, Law 25/1964, of April 29th.

Single transitory provision

All packaging not requiring package design approval acquired following the entry into force of this Instruction shall be accompanied by compliance documentation issued in accordance with article five of this Instruction. In the case of packaging acquired prior to the entry into force of this Instruction, a period of one year is established for such compliance documentation to be made available.

Single additional provision

Apart from whatever checks might be made by the CO's and, where appropriate, the purchaser of the packaging, in accordance with this Instruction, the Nuclear Safety Council may carry out whatever inspections of the packaging manufacturing process it deems to be necessary, pursuant to the provisions of article 2.c) of Law 15/1980, of April 22nd, creating the Nuclear Safety Council.

Single provision of repeal

All standards of equal or lower standing that oppose the present resolution are hereby made null and void.

Final provision

The present Instruction shall enter into force on the day following its publication in the «Official State Gazette».

Madrid, June 10th 2015.- The President of the Nuclear Safety Council, Fernando Marti Scharfhausen.