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The logo for CSN (Comisión Nacional de Seguridad Nuclear) features the letters 'CSN' in a bold, sans-serif font. The 'C' is green, and the 'SN' is blue. To the left of the letters is a vertical bar that is green at the bottom and blue at the top, matching the colors of the letters. A thin blue horizontal line is positioned above the letters.

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The Nuclear Safety Council's Instruction IS-31, of 26 Jun 2011, on the criteria for the radiological control of residual materials generated in nuclear facilities

Article 2.a) of Law 15/1980, of 22 April, creating the Nuclear Safety Council (CSN), confers on this Public Body the faculty to “prepare and approve Instructions, Circulars and Guides of a technical nature relating to nuclear and radioactive facilities and nuclear safety- and radiological protection-related activities.”

Article 2.9 of Law 25/1964, of 29 April, on Nuclear Energy, states that “radioactive waste is any waste material or product for which no use is foreseen and which contains or is contaminated with radionuclides in concentrations or activity levels greater than those established by the Ministry of Industry and Energy (now the Ministry of Industry, Tourism and Trade), following a favourable report from the Nuclear Safety Council.”

On the other hand, Article 76 of the Regulation Governing Nuclear and Radioactive Facilities (RINR) – approved by Royal Decree 1836/1999, of 3 December – establishes that the disposal, recycling or reuse of radioactive substances or of materials containing radioactive substances from any facility must be authorised by the Ministry of Industry, Tourism and Trade's Directorate General for Energy Policy and Mines, following a favourable report from the Nuclear Safety Council.

It also stipulates that the aforementioned authorisation shall not be required when the materials contain or are contaminated with radionuclides in concentrations or activity levels equal or lower than those set by the Ministry of Industry, Tourism and Trade, following a favourable report from the CSN.

The RINR sets in its Appendix I, Section g), Points 1 and 2, the radiological criteria applicable for the clearance of residual materials.

Additionally, it has been established over time in the Radiation Protection Handbooks of nuclear facilities that residual materials which might be potentially contaminated may be managed conventionally when it can be guaranteed that they do not have radioactivity levels greater than the natural radioactive background inherent to the residual material itself or when said levels are below the values set by the competent Authority or any other specific authorisation associated with the operation of the facility.

To achieve greater accuracy, however, the document *Radiation Protection 122 part 1: Practical Use of the Concepts of Clearance and Exemption* (2000) – a publication of a technical nature published by the European Commission where there are included clearance level values for a large number of radionuclides potentially present in the residual materials that are generated in nuclear facilities – has been taken into consideration in the preparation of this Instruction.

Within the scope of the process for the radiological control of residual materials, the clearance levels mentioned in this Publication are used as a quantitative reference allowing to set certain requirements on the radioactive content-measuring techniques and instrumentation such that it is guaranteed that suitable values are obtained for the minimum detectable activity.

Thus, the Nuclear Safety Council has adopted this Instruction so as to develop the aforementioned legal framework and to specify the technical and administrative criteria that must be met by the radiological verifications to which residual materials must be subjected prior to their potential conventional management thereof and, likewise, to define the technical documentation that must be submitted by nuclear facility licensees from a safety and radiation protection standpoint in order to support their applications for

a clearance authorisation.

In accordance with all that has been previously set forth, and by virtue of the legal authorisation envisaged in Section a) of Article 2 of Law 15/1980, of 22 April, creating the Nuclear Safety Council, prior consultation of the affected sectors and after the appropriate technical reports, this Council, in its meeting of the 26th of July of 2011, has agreed the following:

First. Purpose and scope of application

The purpose of this Instruction is to determine:

- The criteria for the radiological control of residual materials, before they exit the radioactive waste areas (RWAs) of nuclear facilities, in order to be conventionally managed.
- The technical documentation that must support the authorisation applications for the clearance of residual materials.

This Instruction is applicable to nuclear facilities in operation or in the process of being dismantled.

Second. Definitions

The definitions of the terms and concepts contained in this Instruction match those contained in the following regulations:

- Law 25/1964, of 29 April, on Nuclear Energy.
- Law 15/1980, of 22 April, creating the Nuclear Safety Council.
- Royal Decree 1838/1999, of 3 December, approving the Regulation Governing Nuclear and Radioactive Facilities.
- RD 783/2001, of 6 June, approving the Regulation on Health Protection against Ionising Radiations.

In addition, the following definitions apply in the context of this Instruction:

Assessment unit: The amount of residual material with a similar history and a similar potential contamination content, on which the radiological control measurements are performed for the decision-making about its subsequent management.

Clearance (of residual materials): An administrative action by means of which certain residual materials having a radioactive content and generated in nuclear or radioactive facilities may be managed as conventional waste without the need for subsequent radiological control.

Clearance levels: The values of surface contamination (Bq/cm²) or activity concentration (Bq/g) below which administrative clearance actions can be undertaken.

Complex geometry: That geometry which does not resemble orthohedral or cylindrical shapes and whose surfaces are not all accessible to the measurement of radiation or contamination.

Conventional management (of residual materials): That management which is not subjected to regulatory radiological control, without prejudice to compliance with other regulations that are applicable to it.

Decision amount: A random variable for decision-making related to whether a physical effect is present or not.

Decision threshold (DT): A value set for the decision amount related to a certain level of confidence which may be variable. When this value is exceeded by the result of a real measurement of a mesurand that quantifies a physical effect, it can be said that the

physical effect is present.

Easy-to-measure radionuclide: A gamma emitter whose activity is correlated with that of other difficult-to-measure radionuclides and can be determined directly by means of non-destructive assays.

Difficult-to-measure radionuclide: A radionuclide whose activity is difficult to determine directly by means of non-destructive assays.

Impacted residual material: That residual material which cannot be classified as non-impacted residual material as a result of a proper categorisation process.

Mean activity concentration: The geometric mean of the concentration of a difficult -to-measure isotope. It is used when the concentration of this isotope cannot be correlated with the concentration of any easy-to-measure isotope.

Mesurand: A particular magnitude that is subjected to measurement.

Minimum Detectable Activity (MDA): The level of actual activity that a specific measurement instrument and technique can be expected to measure 95% of the time.

Non-impacted residual material: That material for which there exists no reasonable possibility of having radioactivity levels greater than those of the natural radioactive background inherent to the material.

Radioactive Waste Area (RWA): An area, premises, enclosure or a part thereof which has physical boundaries or barriers to prevent any transfer of contamination between the inside and the outside, inside of which the generated or stored residual materials are potentially contaminated or activated.

Residual material: That material for which the licensee of the facility where it is located does not envisage any use and must provide proper management. Liquid and gaseous residual materials whose release to the environment must be expressly authorised are excluded.

Sampleable residual material: That material of which it is possible to take a representative portion to perform a measurement, which guarantees that its physicochemical and radiological characteristics can be extrapolated to the totality of the material.

Scaling factor: A parameter derived from a mathematical ratio used for calculating the activity of a difficult-to-measure radionuclide from the activity of an easy-to-measure radionuclide determined by sampling the residual material and analysing the data. Said parameter shall only be valid when it can be presupposed that both radionuclides are correlated.

Simple geometry: That geometry which resembles orthohedral or cylindrical shapes whose surfaces are accessible to the measurement of radiation or contamination.

Third. Criteria for the radiological control of residual materials – before exiting the radioactive waste areas (RWAs) of nuclear facilities – for them to be conventionally managed

Prior to any residual material exiting the RWAs of nuclear facilities to be conventionally managed, it must be guaranteed that it is a non-impacted residual material or that its radioactive content complies with the clearance levels established in a specific authorisation or in the corresponding general provision.

The radiological control of residual materials shall be carried out and supervised by duly qualified staff.

No dilutions or mixtures of residual materials whose main purpose is to attain compliance with the radiological criteria set in this Instruction shall be allowed.

3.1 Categorisation and radiological control of non-impacted residual materials

Residual materials shall be categorized as non-impacted by means of a process of analysis and evaluation of the existing information on the residual material relating to:

- Its characteristics (size, nature, shape, etc.) and its origin and place of provenance within the facility.
- The operations carried out in the areas of the facility where the residual material has been located and the processes in which the material has been involved.
- The results of possible radiological measurements on the residual material or in other locations allowing to obtain relevant information in relation to the ultimate aim.

Unsampleable residual materials having a complex geometry cannot belong to the non-impacted residual material category, unless they are reduced to simple geometry.

Residual materials which have initially been classified as non-impacted as a result of said categorisation process must be subjected, before exiting the RWA, to a radiological control which confirms this classification and which shall specifically consider whether the residual materials are sampleable or unsampleable according to the criteria included in Sections 3.1.1 and 3.1.2 of this Instruction.

For the exclusive purposes of the aforementioned radiological control, the values of the clearance levels included in Table I of the European Commission publication *Radiation Protection 111 Part 1: Practical Use of the Concepts of Clearance and Exemption* (2000) shall be used as reference, as indicated in Sections 3.1.1 and 3.1.2 of this Instruction.

The residual material categorisation process shall be conducted in accordance with each facility's specific operating procedures, taking into account the nature, origin, amounts and frequency of generation of the materials.

3.1.1 Radiological control of sampleable residual materials.

For the radiological control of sampleable residual materials it shall be sufficient to analyse one representative sample of the residual material by means of gamma spectrometry or, when alpha is the most significant type of radiation, to measure the total alpha activity of the sample.

For each gamma isotope that is potentially present in the facility, a minimum detectable activity equal or lower than 50% of the value of the clearance level assigned in the publication *Radiation Protection 122 Part I* must be guaranteed.

For total alpha activity measurements, a minimum detectable activity equal or lower than 50% of the most restrictive clearance level among those assigned to alpha-emitting isotopes in the publication *Radiation Protection 122 Part I* must be guaranteed.

The result of the analysis must confirm that the activity of all isotopes is below the decision threshold.

3.1.2 Radiological control of unsampleable residual materials.

for unsampleable residual materials it shall be sufficient to perform any of the following radiological controls:

- a) Measuring on all surfaces of the residual material, the total beta-gamma or total alpha – when this is the most significant type of radiation – surface contamination, averaged over no more than 300 cm².

The maximum permissible radiation background in the measurement area must guarantee that the minimum detectable activity that can be attained with the measurement equipment is equal or lower than 0.4 Bq/cm² for total beta-gamma

surface contamination or 0.04 Bq/cm² for total alpha surface contamination.

It shall be deemed that the residual material is non-impacted when the net value of the measurement is below the decision threshold associated with the maximum permissible radiation background.

- b) Analysing the residual material assessment unit by means of gamma spectrometry.

For each gamma isotope that is potentially present in the facility, a minimum detectable activity equal or lower than 50% of the value of the clearance level assigned in the publication *Radiation Protection 122 Part I* must be guaranteed.

The result of the analysis must confirm that the activity of all isotopes is below the decision threshold.

3.2 Radiological control of potentially clearable residual materials

If as a result of the categorisation process carried out it is determined that the residual material is impacted, the residual material can be managed as a conventional residue provided the licensee of the facility guarantees compliance with the clearance levels set in the specific authorisation or in the corresponding general provision, considering that:

- a) In each residual material assessment unit it must be verified with a 95% level of confidence that the isotope activity per unit mass (Bq/g) or per unit surface (Bq/cm²) fulfils the expression below:

$$\sum(C_i/ND_i) \leq 1, (1)$$

where

C_i is the isotope activity per unit mass (Bq/g) or per unit surface (Bq/cm²) of every isotope i present in the residual material, obtained by guaranteeing a 95% level of confidence in the determination, and

ND_i is the value of the clearance level established for each isotope i (Bq/g or Bq/cm²).

- b) During the determination of the isotope activity per unit mass (C_i), the minimum detectable activity (MDA) which must be obtained shall range between 10% and 50% of the applicable clearance level.
- c) It shall be deemed that a radionuclide has been detected when a value above its decision threshold is registered, which must be included in the summation of the expression (1).
- d) The use of scaling factors or mean activity concentrations (MACs) for the assignment of the activity to difficult-to-measure isotopes shall previously require to check and justify the applicability of these factors during the operational periods corresponding to the contamination of the batch of residual material whose clearance is being considered.
- e) In order to determine the isotope activity per unit mass or per unit surface of the assessment unit, a representative sample of its content can be taken, its geometric, volumetric and radiological variability being taken into consideration.
- f) On demonstrating compliance with the clearance levels, the considered mass, area or volume of material must be consistent with the hypotheses from which the corresponding clearance levels have been derived; as a general rule, no averaging shall be carried out on masses greater than 1,000 kg or areas greater than 1 m².
- g) The licensee of the nuclear facility must have the corresponding procedures for

the control of the residual materials, where the methodology for the radiological characterisation thereof and the verification of the compliance with the clearance levels are included, in accordance with the requirements listed in this Section.

h) For each of the stages that comprise the clearance process there shall be specific procedures that ensure it is carried out within the framework of a quality control and management system. The licensee shall have a system for the registration of records and reports generated during the clearance process.

i) Prior to shipping the cleared material for it to be conventionally managed, an overall verification of the process shall be conducted on 5% of the generated assessment units. In the event that less than 20 assessment units are generated with the clearance process, this verification shall be conducted on at least one of the cleared assessment units.

Fourth. *Technical support documentation for the applications for clearance authorisation*

The documentation must include at least the following:

- a) The origin and physicochemical and radiological characteristics of the residual materials.
- b) The approximate stock of potentially clearable residual material that is stored in the facility and the data available on its radiological characterisation.
- c) The estimate of the average amounts of potentially clearable residual material generated in the facility on a yearly basis.
- d) The classification of the residual materials from the point of view of conventional management and the description of the pathways for managing them under regulations in force.
- e) A proposal of clearance levels, which might be done by analysing those international references which might be applicable or by carrying out a radiological impact assessment study, where the existing management alternatives are analysed and clearance levels are derived according to the established radiological criteria.
- f) The methodology and the procedures that will be followed to perform the radiological characterisation of the residual materials and to verify compliance with the clearance levels, in accordance with the technical criteria set in Section 3.2 of this Instruction.
- g) The scope and the methodology that will be followed to perform the quality control applicable to the residual materials clearance process.
- h) The conventional management pathway that is proposed for the residual materials once they are cleared.

Fifth. *Infractions and sanctions*

This Nuclear Safety Council Instruction is binding in accordance with the establishment of Article 2.a) of Law 15/1980, of 22 April, creating the Nuclear Safety Council, such that the failure to comply with it shall be punished in accordance with the provisions of Chapter XIV (Articles 85 to 93) of Law 25/1964, of 29 April, on Nuclear Energy.

Sole Repealing Provision

Any rule of equal or lower level that opposes the present Instruction is repealed.

Sole Final Provision

The present Instruction shall come into force on the day following that of its publication in the "Official State Gazette".

In Madrid, on the 26th of July of 2011.- Carmen Martínez Ten, the President of the Nuclear Safety Council.