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III. OTHER PROVISIONS

NUCLEAR SAFETY COUNCIL

4630 *Instruction number IS-40 of the Nuclear Safety Council, April 26th 2016, regarding documents that must be provided when requesting authorisation for commercialisation or providing technical assistance of appliances, equipment, and accessories that contain radioactive material or are generators of ionising radiation.*

Article 2(a) of the Law 15/1980, April 22nd, by which the Spanish Nuclear Safety Council was created, attributes to this Public Entity the power 'to draw up and approve technical instructions, circulars, and guides relating nuclear and radioactive facilities, and activities relating to nuclear safety and radiation protection'.

In Article 74(2) of the Royal Decree 1836/1999, December 3rd, which approves the Regulation on Nuclear and Radioactive Facilities, it is explained which documents are required to process an application for the authorisation for commercialisation or provide technical assistance for devices, equipment and accessories that contain radioactive material or generators of ionising radiation.

This Instruction explains and extends the aforementioned documents, incorporating criteria that the Nuclear Safety Council considers must be met to produce a favourable prescriptive report. It shall set the limits and conditions in terms of radiation safety and protection that the authorised institutions will apply when commercialisation or providing technical assistance for devices, equipment, and accessories that contain radioactive material or generators of ionising radiation.

On the basis of the above and in accordance with Article 2(a) of the Law 15/1980, April 22nd, by which the Spanish Nuclear Safety Council was created, in consultation with all the sectors concerned and after the consideration of corresponding technical reports, the Council agreed the following on April 26th, 2016:

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1. *Subject matter and scope of application.*

The subject matter of the present Instruction is to extend the content of the documentation that should be provided in support of an application for authorisation for commercialisation or provide technical assistance as preventive or corrective maintenance of devices, equipment and accessories that contain radioactive material or generators of ionising radiation. It will also establish acceptance criteria for the same matters.

This Instruction does not apply to sales companies or companies that provide technical assistance and are governed by the Royal Decree 1085 / 2009, July 3rd; it approving the Regulation on facilities and use of x-ray machines for medical diagnosis.

Organisations that require radioactive material or sources to be stored on their premises for commercialisation activities or the provision of technical assistance, or those that generate ionising radiation must hold an authorisation as a radioactive facilities.

2. *Definitions.*

The definitions of terms and concepts used in this Instruction correspond to the definitions written in:

Law 25/1964, April 29th, on Nuclear Energy.

Law 15/1980, by which the Spanish Nuclear Safety Council was created.

Royal Decree 1836/1999, December 3rd, on the approval of the Regulation.

3. *Documentation and information.*

For the purposes of this Instruction, the documentation that an organisation should provide to become authorised for commercialisation or providing technical assistance for appliances, equipment, and accessories that contains radioactive material or generate of ionising radiation, are the following:

a) Identification of the company or organisation: business name, tax identification number, address, certificate of registration in the Commercial

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Register, and justification of the company purpose; being all this information referred to the Spanish State.

b) Memorandum of the activities that will be carried out. An accreditation shall be provided to prove an existing agreement between the organisation and the manufacturer of the equipment, which will detail the scope of their commercialisation activities or provide technical assistance for their equipment, as well as the commitment to remove the radioactive material at the end of the equipment's useful life, when applicable.

When providing technical assistance for certain equipment, if a direct agreement with the manufacturer is not available, then it must be proven that there is an existing agreement with other organisations that are at the same time accredited by the manufacturer, guaranteeing that manuals, original parts for original equipment and information about changes that have occurred related to the licensing in the country of origin, with regard to its manufacture, marketing and use.

c) Where appropriate, details of the company's experience in business activities of the same nature.

d) Organisation of staff and company rules. The organisational chart of the company should be attached, with a description of the functions and responsibilities assigned to each person, clearly showing the technical responsibility and radiation protection of workers.

According to the required activities, the company will have to define the standards of operation that will be applied to commercialisation activities, technical assistance as preventive and corrective maintenance and tests of acceptance, and the removal and destruction of equipment, if applicable.

e) Relationship to the staff technicians, in terms of their degrees, qualifications, and professional experience. The qualifications of the staff will be assessed based on the type of equipment, and they should demonstrate their skills for each part of equipment. Therefore, the manufacturer of the equipment or a instructor recognised by the manufacturers shall issue specific documentation to acredite whether the staff members are capable and have been properly trained to carry out the technical assistance on different models.

In addition, the staff must hold recognised training in radiation protection. Those organisations which, due to their activities, do not require authorisation of radioactive facilities, and therefore do not have staff with the supervisor or operator licenses, while taking into account that this formation is not officially regulated, the radiation protection training is considered equal to:

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The radioactive facilities operator training with its applicable specialisation, accredited after the completion of a course approved by the Nuclear Safety Council, in the cases of performances on equipment that requires type approval or does not require type approval, that in some of the performances of maintenance work outside the conditions that are contained in this agreement.

- The training defined for the module IB-Basic areas of the Level of radioactive facilities operator in the Appendix B of the CSN Safety Guide GS-05.12, 'Homologation of training courses for the supervisors and operators of radioactive facilities', recognised after the completion of the corresponding contents of the module of a course accepted by the Nuclear Safety Council in the matter of performance on equipment that requires type approval that in none of the performances of maintenance work outside the conditions that are contained in this agreement.

In the case of foreign workers in Spain, assistance and academic progress are fair reasons to take any course with contents of radiation protection, provided that the course contents is related to either of the two previous options before mentioned and depending on the type of equipment that will be used.

f) List of facilities, equipment and material resources available in the company or entity to perform its activities. This relationship must ensure that the staff carrying out the activities, according to the Maintenance Manual, have the necessary means to maintain the safety of radiation equipment.

Moreover, companies should attach the technical characteristics of the equipment for detecting and measuring radiation or contamination, suitable for carrying out the radiation control during the development of the technical assistance activities.

g) If applicable, procedures to ensure radiation protection of workers who are exposed because of the tasks that will be carried out, This could include procedures related to: the management of personal dosimetry (justifying whether or not this is applicable), the performance status of incidents and/or radiation accidents, the use, testing and calibration of equipment for detecting and measuring radiation or contamination, and the use of additional shielding or any other means of radiation protection that may be required.

A maintenance manual containing the technical procedures for each task will be presented, the acceptance criteria according to current European

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legislation, a checklist of points to check in the maintenance periods of the equipment and a certificate profile that will be provided to the customer.

4. *Offences and penalties.*

This Instruction of the Nuclear Safety Council is legally binding and is in accordance with the Article 2(a) of the Law 15/1980, April 22nd, by which the Spanish Nuclear Safety Council was created. Therefore, failure to comply with this Instruction will be sanctioned as established in the Articles 85-93 of the Chapter XIV of Law 25/1964, on Nuclear Energy.

Sole additional provision.

This Instruction shall be applied to those organisations that commercialise or provide technical assistance for devices, equipment and accessories that incorporate radioactive material or generate ionising radiation, wanting to obtain an operating permit from the date that this Instruction come into force. The entities that already have the permit, will have this Instruction applied in subsequent requests for modification.

Sole final provision.

This Instruction shall come into force on the day following its publication in the 'Official State Gazette'.

The President of the Council of Nuclear Security, Fernando Marti Scharfhausen. Madrid, April 26th 2016.