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THE NUCLEAR SAFETY COUNCIL

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(To be filled out in the "Official State Gazette")	

SUMMARY

In Madrid, on the 2nd of April of 2008

Nuclear Safety Council's Instruction IS-18, of 2nd April 2008, on the criteria applied by the CSN to demand from the licensees of radioactive facilities the reporting of radiological events and incidents.

TEXT

(Escribase a dos espacios)

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, modified by Law 33/2007, of 7th November, confers on this Government Agency the faculty to "prepare and approve Instructions, Circulars and Guides of a technical nature relating to nuclear and radioactive facilities and nuclear safety- and radiation protection-related activities".

Article 73.2.b) of Royal Decree 1836/1999, of 3rd December, approving the Regulation governing nuclear and radioactive facilities, modified by Royal Decree 35/2008, of 18th January 2008, and the conditions of the radioactive facility operating license state the obligation of the licensee of a radioactive facility to inform the

Directorate-General for Energy Policy and Mines and the CSN of any event related to the occurrence of accidents, where the circumstances thereof shall be detailed.

The thirty-fourth Ruling of the Chamber of Deputies' Industry, Tourism and Trade Commission, dated 14th December 2004, and the twenty-fifth and thirty-seventh Rulings of the same Commission, dated 12th December 2007, urge the CSN to "prepare a guide for the reporting of accidents in radioactive facilities in order to systematise the operating experience in radioactive facilities, similar to that developed for nuclear power plants".

According to what has been set out, in order to comply with the Congress of Deputies' mandate, and there being a need for the technical clarification as to what are the events that, in accordance with the provisions of the Regulation governing nuclear and radioactive facilities and its modification by Royal Decree 35/2008, of 18th January, must be known by the Nuclear Safety Council according to their significance for safety or radiological protection, the present Instruction regulating the criteria for reporting the mentioned events has been issued.

By virtue of the all the above and in accordance with the legal authorisation envisaged in Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, modified by Law 33/2007, of 7th November, prior consultation of the affected sectors and after the appropriate technical reports, this Council, during its meeting on the 23rd of January of 2008, has agreed the following:

First. Purpose. Scope of application.- The purpose of the present Instruction is to set the criteria that will be required by the Nuclear Safety Council to the licensees of radioactive facilities in relation to radiological events that happen in their facility and of which they must inform said Council, in accordance with the provisions of Article 73.2 b) of the Regulation governing nuclear and radioactive facilities and its modification by Royal Decree 35/2008, of 18th January.

This Instruction shall apply to all radioactive facilities in operation.

The following cases are excluded from reporting:

1. Events that have taken place in facilities with X-ray equipment for medical diagnosis, except those that apply due to being included in the external exposure criterion mentioned in Section Fifth A.

2. Those events that have happened during medical exposures, provided no failures due to the loss of barriers, degradation of systems, failure of operational radiological protection equipment or procedures occurred during the event or they could have given rise to the exposure of third parties.

All of it without prejudice to the reporting requirements which are mandatory according to the application of other regulations.

Second. *Definitions.*-

Radiological event: an event affecting structures, systems or components of radioactive facilities which can actually or potentially create a risk of undue exposure for radiation workers and the public.

Medical exposure: the exposure of people as established in Article 1.1 of Royal Decree 815/2001, on the justification for the use of ionising radiations for the radiological protection of people on the occasion of medical exposures.

Patient: the person that requires medical care and is subjected to professional care for preserving or recovering his/her health, as established in Article 3 of Basic Law 41/2002, of 14th November, regulating the autonomy of the patient and the rights and obligations as regards clinical information and documentation.

Source category: according to the definition set in the International Atomic Energy Agency's (IAEA) Safety Guide RS-G-1.9, it is the relative level of risk associated with a radioactive source based on the potential damage that it can cause if it is not handled in a safe manner.

The remaining definitions of the terms and concepts used in the present Instruction match those contained in the following legal and regulatory documents:

Law 25/1964, of 29th April, on Nuclear Energy (BOE no. 107, of 4th May 1964, second Article), modified by Law 33/2007, of 7th November, reforming Law 15/1980, of 22nd April, creating the Nuclear Safety Council.

Law 15/1980, of 22nd April, creating the Nuclear Safety Council (BOE no. 100, of 25th April 1980), modified by Law 33/2007, of 7th November (BOE no. 268, of 8th November 2007).

Royal Decree 1838/1999, of 3rd December, approving the Regulation governing nuclear and radioactive facilities (BOE no. 313, of 31st December 1999).

Royal Decree 783/2001, of 6th June, approving the Regulation on health protection against ionising radiations (BOE no. 178, of 26th July 2001).

Royal Decree 1891/1991, of 30th December, on the installation and use of X-ray devices for medical diagnosis (BOE no. 3, of 3rd January 1992).

Royal Decree 229/2006, of 24th February, on the control of sealed, high-level radioactive sources and orphan sources (BOE no. 50, of 28th February 2006).

Code of Conduct on the safety and security of radioactive sources (International Atomic Energy Agency), Vienna 2004.

Third. *Criteria for the reporting of radiological events in a radioactive facility.*- The classification specified in Sections Fourth and Fifth will be followed for event reporting purposes.

Once the event is known, the maximum reporting time is 1 hour for events included in Section *Fourth* and within the first 24 hours for those included in Section *Fifth*.

Apart from the reporting, the licensee will send a report within 30 days on the event containing all the complete information. The CSN will made available to the users a model for sending that information ..

The reporting shall be carried out in accordance with that established in the Attachment.

All events shall be reported to the Nuclear Safety Council's Emergency Room (SALEM); the proper authority in the Autonomous Community where the event took place shall also be reported. The CSN will have a list of the authorities to be reported in each Autonomous Community at the disposal of users..

At any time, the CSN may require additional information on an event or the corresponding reviewed reports if it deems that this is necessary to understand it.

Should discrepancies arise between the CSN and the licensee about the reportability of an event, the opinion of the CSN shall prevail and the reporting shall be carried out in accordance with the criterion indicated in a reasoned manner by the CSN.

The requirements indicated in the preceding paragraphs must be added to the Emergency Plan or the Operation Handbook of the radioactive facility.

Fourth. *Immediately reportable events (1 hour).*- This class includes those events that occur in a radioactive facility and might require outside intervention by e.g. fire-fighters or policemen:

A. Operation.

Events inside the radioactive facility, the control of which is not guaranteed at some point in time and might constitute a threat to the safety of the facility, such as a fire in the facility lasting more than 10 minutes, internal flooding near the location of radioactive equipment and/or material, or the release of toxic or explosive substances inside the facility.

B. External events.

A natural or external phenomenon that might constitute a threat to the safety of the radioactive facility, such as intense winds or rainfall, an uncontrolled fire near the radioactive facility, the emission of dangerous toxic substances that give rise to inadmissible concentrations in the radioactive facility, or explosions in the vicinity of the radioactive facility.

C. Security.

1. The disappearance (loss or theft) of radioactive sources of category 1, 2 or 3, such as those used in teletherapy, irradiators, industrial gammagraphy, industrial process controls, high-dose rate brachytherapy equipment, or explorations.

2. The appearance of orphan sources of category 1, 2 or 3.

3. The events mentioned in Sections C.1 and C.2 involving sources which, even though not belonging to categories 1, 2 or 3, are considered high-activity sources in accordance with Royal Decree 229/2006, of 24th February, on the control of sealed, high- activity level radioactive sources and orphan sources, shall also be reported within 1 hour.

4. Threats to security, such as intrusion or sabotage attempts, intentional degradations of security, the blocking of accesses, or plausible bomb threats.

Fifth. Events reportable within 24 hours .- This class includes events that take place in a radioactive facility and do not require the immediate intervention of external people even though they might have radiological consequences on people, the premises, the equipment or the environment:

A. External exposure, and contamination.

1. Any event in which a radiation worker or a member of the public might have received, in a preliminary estimate, a dose by external irradiation or by internal

contamination exceeding, during a single exposure, the dose limits set under the Spanish Law.

2. Operational events in which there is a potential risk of receiving an undue dose due to the failure of equipment, damaged equipment, the failure of the source to retract to its shielded or storage position, the uncontrolled access to places with high levels of radiation, such as irradiation rooms or enclosures, the failure of safety systems in the facility, or human errors.

3. Any circumstance when the licensee considers that a worker might have exceeded, due to accumulated exposures, the legal limits.

4. Events due to spills or releases of radioactive material because of a leakage of the source, the vial, or another material containment system that give rise to the contamination of free-access areas, where it is necessary to reclassify the affected area during 24 hours due to any of the dose rate or contamination criteria.

5. Any other event not included in the previous points that might give rise, in the licensee's opinion, to undue exposures to members of the public, such as a rupture or failure of the controlled discharge system, an out-of-control patient with an incorporated radioactive source or material, or the appearance of radioactive material in free-access areas.

B. Spills.

1. Any unplanned or uncontrolled discharge of radioactive material to the outside of the facility.

2. Exceeding the discharge limits in the specifications of the radioactive facility's license.

C. Safety systems.

Any situation that has a potential impact on the safety systems of the facility, such as interlocks, monitors or alarms.

D. Security.

1. The disappearance (loss or theft) of sealed radioactive sources or the appearance of orphan sources of category 4, such as those used in low-dose rate brachytherapy, mobile soil density and humidity measurement equipment, and industrial process controls, and unsealed orphan sources, such as those used in nuclear medicine and laboratories. Provided they are not considered high-activity sources in accordance with Royal Decree 229/2006, of 24th February, on the control of sealed high-level radioactive sources and orphan sources, which Section C.3 of Article Four of this Instruction applies to.

2. Any event where the licensee deems that a failure in the control of radioactive material or of the means that guarantee the security of the radioactivity facility has occurred.

E. Other.

1. The discovery of design, construction, assembly, operation, maintenance or other flaws, provided they could have prevented the performance of the safety function of safety structures, systems or components.

2. The discovery of deficiencies in the performance of the facility's personnel or in the operation procedures, provided they could have prevented the performance of the safety function of safety structures, systems or components.

3. Any other event not covered in the preceding points that might have, in the licensee's opinion, significance for radiological safety.

Sixth. *Infractions and sanctions.*- The present Nuclear Safety Council Instruction is binding in accordance with that established in Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, such that the failure to comply with it shall be

punished in accordance with the provisions of Chapter 14 (Articles 85 to 93) of Law 25/1964, of 29th April, on Nuclear Energy, in the phrasing given to it by Law 33/2007, of 7th November, reforming Law 15/1980, of 22nd April.

Sole Transitory Provision.- A period of one month from the publication of this Instruction is set for the licensees to add the reporting requirements to the Emergency Plan or the Operation Handbook of the radioactive facility.

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”.

Which I announce to inform you for all pertinent purposes.

In Madrid, on the 2nd of April of 2008.- Carmen Martínez Ten, the President of the Nuclear Safety Council.

THE SECRETARY GENERAL OF THE NUCLEAR SAFETY COUNCIL

Add to the “Official State Gazette”.

In Madrid, on the 9th of April of 2008

THE PRESIDENT

Carmen Martínez Ten

ATTACHMENT

The initial reporting may be conducted over the phone. Subsequently, it must be carried out in writing, by fax, including the following information:

- ID of the person that calls. Contact telephone number.
- ID of the facility.
- Description of the event, including the time and date thereof.
- Exact location of the event.
- Isotope, activity, physical and chemical form of the affected material, make and model of the radiation generating equipment.
- Category of the radioactive source involved.
- Any information available on people exposure.
- Measures adopted by the licensee.