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Nuclear Safety Council (BOE no. 37, of 12/02/2008)

Nuclear Safety Council's Instruction IS-16, of 23rd January 2008, regulating the periods of time which documents and records of radioactive facilities must be remain filed for.

TEXT

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, confers on it, after the reform introduced by Law 33/2007, of 7th November, 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 72 of the Regulation on nuclear and radioactive facilities approved by Royal Decree 1836/1999, of 3rd December, establishes that "the licensee is obliged to file all documents and records that are required in this Regulation, other applicable provisions and the permits granted for the periods of time that are set in each case".

Article 38 of the Regulation on health protection against ionising radiations, approved by Royal Decree 783/2001, of 6th July, establishes that the dosimetric history of exposed workers, the documents corresponding to dose evaluation and the measurements of monitoring equipment, and the reports relating to the circumstances and measures adopted in cases of accidental or emergency exposure must be kept filed by the license holder of the practice until the worker has or would have reached seventy five years of age and never for a period of time shorter than thirty years from the date the worker stopped taking part in those activities that meant his/her classification as an exposed worker.

Likewise, Article 44 of the same Regulation establishes that medical histories shall remain filed until the worker has or would have reached seventy five years of age, and never for a period of time shorter than thirty years after he/she stopped taking part in the activity, in the Prevention services that perform the function of monitoring and controlling the health of workers corresponding to the centres where those people provide or have provided their services, and shall be at the disposal of the competent authority and the worker himself/herself.

Since the Regulation only sets the time which dosimetric and medical histories must remain filed for, the issuance of the present Instruction is necessary in order to also regulate the time which the other documents and records that the licensee of a radioactive facility must remain filed for in accordance with said Article 72 of the Regulation governing nuclear and radioactive facilities

The periods set in Safety Guide GS-9.2 in relation to the management of solid waste materials with radioactive contents have been considered when establishing the periods of time during which the different documents and records of radioactive facilities must remain in the custody of the licensee; for the rest of cases, the periods set in other countries' regulations and the

operating experience from these facilities in the possession of the CSN have been taken as reference.

On the other hand, although this Instruction falls within the scope of radioactive facilities and not within that of health care units - which the different Royal Decrees that are used by the corresponding health authorities refer to, it has been deemed convenient that the time filing criteria be the same in order to avoid confusing situations for the licensees, taking into account that the final recipients of both the Instruction and the mentioned health regulations are the same in the case of medical radioactive facilities.

In this sense, it has been taken into consideration that, in accordance with Royal Decree 1566/1998, establishing the criteria for quality in radiotherapy, all reports mentioned therein - among others, those relating to repairs or interventions in radiation-generating units - must be kept filed for a period of thirty years.

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, after the reform entailed 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 stipulated the following:

First. Purpose and scope of application.- The purpose of the present Instruction is to define the period of time during which the documents and records that the licensee of a radioactive facility must file in accordance with Article 72 of the Regulation governing nuclear and radioactive facilities must remain under the custody thereof.

This Instruction will apply to the licensees of the radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes defined in Article 34 of the Regulation mentioned in the preceding paragraph.

This Instruction does not apply to medical radiodiagnostic equipment, the use of which is regulated by Royal Decree 1891/1991, of 30th December.

Second. Definitions.- The definitions of the terms and concepts used in the present Instruction match those contained in the following legal documents:

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

Law 15/1980, of 22nd April, creating the Nuclear Safety Council.

Law 33/2007, of 7th November, reforming Law 15/1980, which modifies the previous two Laws.

Royal Decree 1838/1999, of 3rd December, approving the Regulation governing nuclear and radioactive facilities.

RD 783/2001, of 6th June, approving the Regulation on health protection against ionising radiations.

Royal Decree 229/2006, of 24th February, on the control of sealed, high-level radioactive sources and orphan sources.

Third. Documents and records. Holding periods.- Every licensee of a radioactive facility must keep under its custody the documents and records that apply thereto for the periods of time that are set below:

1. Until the radioactive facility is decommissioned:

1.1 A copy of the license currently in force with its limits and conditions as well as of the documents attached to the application for obtaining said license and defined in Article 38 of the Regulation governing nuclear and radioactive facilities, and any other that has been necessary to license the facility or, where appropriate, the subsequent modifications of these documents that have taken place and which the Nuclear Safety Council is aware of.

1.2 The operation logbooks generated during at least the last five years of operation of the facility.

1.3 The records relating to the updated list of personnel generated during at least the last two years of operation of the facility. These records must contain, together with the ID of every worker, his/her classification in accordance with the Regulation on health protection against ionising radiations, his/her job and, where appropriate, if he/she has a supervisor/operator license.

1.4 All records mentioned in this Instruction, when the decommissioning takes place before the holding period set in each case.

2. At least two years from the date on which they were generated.

2.1 The records relating to the updated inventory of radioactive material and equipment. The record-updating frequency shall be that set in each case in either the corresponding license or the radioactive facility licensing documents.

2.2 The records relating to the controls of radiation and contamination levels of the facility's premises. The records must include: the date and the results of the controls as well as the ID of the piece of equipment used and of the person or entity that carried them out.

2.3 The controls of radiation and contamination levels shall be carried out with the periodicity established in each case in the corresponding license or in the radioactive facility licensing documents.

2.4 The records relating to the verifications of the suitability of the biological shielding and safety systems of the facility. These verifications shall be carried out with the periodicity established in each case in the corresponding license or in the radioactive facility licensing documents.

2.5 In the case of facilities authorised to own and use equipment containing radioactive sources, ionising radiation-generating equipment or particle accelerators, the records relating to (preventive or corrective) maintenance operations, except those mentioned in point 5.3. The records must at least contain the following: the date and the ID of the maintenance operation performed as well as that of the authorised person and/or entity that carried it out and the state in which the piece of equipment was left in.

2.6 The records on the planning of the works to be carried out by operations personnel for dose optimisation. The records shall follow that established in the corresponding license or in the radioactive facility licensing documents.

2.7 The records on the inspections carried out by supervisors of industrial gammagraphy over in the field operations conducted by operators and assistants. The frequency for carrying out these inspections shall be that set in the corresponding license or in the radioactive facility licensing documents. The records must at least include the following: the ID of the inspected personnel, the date, the results, and the corrective actions.

2.8 The records relating to the readings of direct-reading dosimeters of personnel operating a mobile, industrial gammagraphy radioactive facility (operators and assistants). The records shall be carried out according to that established in the corresponding license or in the radioactive facility licensing documents.

2.9 Any other record that is imposed on the licensee of a radioactive facility in the license thereof or in the legislation that applies thereto, unless another condition is imposed in said license or legislation.

3. At least two years from the date of the transfer of radioactive material, equipment or waste.

3.1 The records corresponding to the storage of radioactive waste for it to decay and its removal by an authorised company must be kept for at least two additional years from the date on which it was handed over to the final waste disposal companies.

These records must provide the data necessary to justify compliance with the specifications included in the license.

3.2 In the case of facilities authorised to own and use radioactive sources and equipment, the records relating to the receipt and transfer thereof must be kept for at least two years from the date on which they were transferred. Every record must include, in addition to the ID of the radioactive source or piece of equipment (model, serial number, radionuclide, estimated activity),

the destination of the sources not longer in use and the origin of the new ones as well as the dates of receipt or transfer.

3.3 The records of the new sources that are used during implants in medical brachytherapy facilities must be kept for at least two years from the date said sources were deregistered from the facility's inventory.

3.4 In the case of temporary hand implants, the records shall at least include: the number and activity of the implanted sources, the dates on which the implants were made, the dates when the sources were removed from the patients and returned to their storage at the radioactive facility, as well as the personnel involved in said operations.

In the case of permanent implants, the records shall include the number and activity of the implanted sources and the dates of the implants.

All of this is independent from the records on implants that must be part of the clinical history of the patients.

4. At least one year from the date on which they were generated.

4.1 The records relating to the location at all times of mobile radioactive equipment. Said records must contain, in addition to the location, the ID of the piece of equipment and of the operations personnel in charge thereof.

5. At least five years from the date on which they were generated.

5.1 In the case of radioactive facilities dedicated to the import and marketing of radioactive equipment and material, the records relating to the import (date of entry) and supply (date of exit) and the data relating to the replacement of sources, the management of sources at their end of life and the provenance of the new ones.

5.2. Every licensee of a radioactive facility having a license to provide after-sales services to ionising radiation-emitting equipment must keep the records of after-sale service certificates for at least five years from the date on which the certificate was issued. The certificates shall be issued in accordance with that established in the corresponding license or in the radioactive facility licensing documents.

5.3 The records relating to each of the activities envisaged in the plan for the continuous training of exposed workers, which shall be conducted with the periodicity set in the corresponding license. The records shall include at least the training programmes imparted, the contents thereof and the attendees.

5.4 The records relating to the disposal of solid waste materials with radioactive contents which are managed in accordance with the provisions of Order ECO/1449/2003, of 21st May, on the

management of solid waste materials with radioactive contents generated in 2nd and 3rd category radioactive facilities where unsealed radioactive isotopes are handled and stored, and in Safety Guide GS-9.2. These records must provide the data necessary to justify compliance with said Ministerial Order.

5.5. The records relating to controlled discharges of radioactive effluents. These records must provide the data necessary to justify compliance with the specifications included in the license.

6. Until the certificate or document that guarantees them has been replaced by another one.

6.1 The records on the leak-tight tests of sealed radioactive sources until the radioactive source in question has been transferred. The periodicity for conducting leak-tight tests shall be that set in each case in either the corresponding license or the radioactive facility licensing documents. Every record must include the ID of the radioactive source (model, serial number, radionuclide, estimated activity), the result of the test, the date, and the authorised person or entity that carried it out.

6.2 The records relating to the verifications and calibrations of the radiation and contamination detection and measurement equipment in use. The verifications and calibrations of radiation and contamination detection and measurement equipment shall be carried out in accordance with that established in the corresponding license or in the radioactive facility licensing documents. The records will show the person or entity that performed them.

7. Until the radioactive source has been transferred.

7.1 The standardised record sheet that the licensee must keep, in accordance with Royal Decree 229/2006. on the control of sealed, high-level radioactive sources and orphan sources, of each of the sources of this type under its responsibility.

8. For a period of 30 years.

8.1 The records relating to the (preventive or corrective) maintenance operations on the equipment used to give treatment in medical radiotherapy radioactive facilities.

Fourth. Software.- When the documents and/or records are completed in software form, safety mechanisms or systems must be in place to appropriately guarantee the following:

The integrity, authenticity, quality, protection and conservation of the data contained in them. In particular, they shall guarantee the ID of the people that enter data therein and the control of access thereto.

Fifth. 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.

Sole Final Provision. Entry into force.

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

In Madrid, on the 23rd of January of 2010.- Carmen Martínez Ten, the President of the Nuclear Safety Council.