The CSN provides users of this website with an unofficial translation of the law in question. You are therefore advised that this translation is for your information only and may not be entirely up to date when you consult it. For official texts, look up the law in the Boletín Oficial del Estado, where you can find laws in any of the official languages of the State of Spain.

CSN

El CSN pone a disposición de los usuarios de esta web una traducción no oficial del texto de la norma de referencia. Se advierte, por tanto, de su carácter puramente divulgativo, y de la posibilidad de que no se encuentre debidamente actualizada en el momento de su consulta. El texto oficial es el publicado en el Boletín Oficial del Estado en cualquiera de las lenguas oficiales del Estado español.

III. OTHER PROVISIONS

THE NUCLEAR SAFETY COUNCIL

8779

Nuclear Safety Council's Instruction IS-24, of 19th May 2010, regulating the filing and periods of retention of the documents and records of nuclear facilities.

Article 2.a) of Law 15/1980, of 22nd April, creating the Nuclear Safety Council, reformed by Law 33/2007, of 7th November, confers on this public entity 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".

The Regulation Governing Nuclear and Radioactive Facilities, approved by Royal Decree 1836/1999, of 3rd December, modified by Royal Decree 35/2008, of 18th January, states in its Article 72 that: "The license holder is obliged to file all documents and records that are required in this Regulation, other applicable provisions and granted permits for the periods of time set in each case."

CSN Instruction IS-19, on the requirements of the management system of nuclear facilities, establishes that nuclear facilities must have document- and record-control processes.

UNE Standard 73-401:1995 "Quality Assurance in Nuclear Facilities" includes among its criteria the need for preparing quality assurance records and records on the collection, filing and keeping thereof.

CSN Safety Guide GS-1.13 "Content of NPP Operation Handbooks" indicates in Section G "Document Keeping and Filing" that Operation Handbooks must identify the type of documents and records that must be kept and the retention periods according to whether they are significant for the nuclear safety or radiological protection of the facility in the different phases of project, operation and decommissioning thereof.

CSN Safety Guide GS-10.2 (Rev. 1) "Documentation System for Documents Subjected to Quality Assurance Programmes in Nuclear Facilities" considers an acceptable practice for the implementation of the documentation system of a nuclear facility the application of IAEA Safety Guide 50-C/SG-Q3 "Document and Record Control" or equivalent quality assurance criteria and requirements from the country of origin of the project. This IAEA Guide has been recently replaced by Safety Guide SG-G-3.1 "Application of the Management System for Facilities and Activities".

As regards regulations from the country of origin of the project, the industry has used ANSI Standard 45.2.9 "Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants", ASME Standard NQA-1, Requirement 17, "Quality Assurance Records", and Regulatory Guide 1.88 «Collection, Storage and Maintenance of Nuclear Power Plant QA Records" as a reference.

The lack of a specific Spanish rule, together with the differences in the scopes and contents of Spanish nuclear facilities' Operation Handbooks with regard to the identification of the documents and records that must be kept, make it necessary to issue the present Instruction in order to specify the types of records and documents to be kept, the conservation periods and the conditions for the filing thereof.

The requirements set in the present Instruction are based on Standard ASME-NQA-1-2008, Safety Guide GS-G-3.1 "Application of the Management System for Facilities and Activities", Safety Guide GS-G-3.3 "The Management System for the Processing, Handing and Storage of Radioactive Waste", Safety Guide GS-G-3.4 "The Management System for the Disposal of Radioactive Waste" and Safety Guide GS-G-3.5 "The Management System for Nuclear Installations". Said documents are acceptable references for the implementation and application of this Instruction.

Since this Instruction is applicable to both the documents and records generated at the nuclear facilities themselves and those generated in engineering companies, service providers, inspection agencies and manufacturers and given that license holders are responsible for observing it, there must be contractual agreements with these providers so that the documents and records related to the nuclear safety and radiological protection of the facility that cannot be transferred to the licensee for some reason are kept by the providers and placed at the disposal of the proper Authorities under the conditions required in this Instruction.

The present Instruction complements the following Instructions previously issued by the CSN: IS-04, of 5th February 2003, regulating the transfers, filing and safekeeping of documents related to radiological protection in nuclear facilities upon their dismantling and decommissioning, IS-13, of 21st March 2007, on the radiological criteria for the release of nuclear facility sites, and IS-16, of 23rd January 2008, regulating the periods of time which the documents and records of nuclear facilities must remain filed for.

By virtue of 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, according to the wording given by Law 33/2007, prior consultation of the affected sectors and after the appropriate technical reports, this Council, in its meeting of the 19th of May of 2008, has stipulated the following:

First. *Object and scope of application.*- The purpose of the present Instruction is to identify the documents and records generated during the different site analysis, project, construction, operation and dismantling phases of a nuclear facility that must be kept according to Article 72 of the Regulation Governing Nuclear and Radioactive Facilities. Likewise, the present Instruction sets the periods and conditions for the filing thereof, the license holder being responsible for observing them.

This Instruction will apply to both the documents and records generated at the nuclear facilities themselves and those generated in the engineering companies, service providers, inspection agencies and manufacturers that are related to the nuclear safety and radiological protection of the facility.

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

Law 25/1964, of 29th April, on Nuclear Energy (BOE No107, 4 May 1964).

Law 15/1980, of 22nd April, creating the Nuclear Safety Council (BOE No1000, 25 April 1980).

Royal Decree 1838/1999, of 3rd December, approving the Regulation Governing Nuclear and Radioactive Facilities (BOE No313, 31 December 1999).

RD 783/2001, of 6th June, approving the Regulation on Health Protection against Ionising Radiations (BOE No178, 26 July 2001).

UNE Standard 73 401:1995 “Quality Assurance in Nuclear Facilities”.

Safety Instruction IS-19on the requirements of the management system of nuclear facilities (BOE No43, 19 February 2009).

Royal Decree-Law 14/1999, of 17th September, on electronic signature (BOE No224, 18 September 1999).

In addition to the above, other terms are used that are understood as follows within the context of this Instruction:

File: the place where documents and records are stored and safeguarded.

Documents and records to be kept: the nuclear safety- or radiological protection-related documents and records generated during the site analysis, construction, operation and dismantling phases of a nuclear facility that must be filed under the proper conditions for a certain, specified period of time.

Safety-significant structures, systems and components (SSCs). They comprise:

1. Those SSCs the malfunction or failure of which could cause an undue exposure to radiation for site personnel or members of the public.
2. Those SSCs that prevent planned operational events from giving rise to accident conditions.
3. Those SSCs whose aim is to mitigate the consequences of accidents caused by a malfunction or failure of SSCs.

Non-repudiation: the capacity to ascertain the authorship of a message or piece of information, preventing the author from denying the existence of its reception or creation. Among its characteristics are those of checking the creation and origin of the contents or of having the documents that prove the sending or reception of messages.

Retention period: the length of time which a document or record must be kept filed for.

Record carrier: the medium that contains the document; it can be a sheet of paper, an X-ray, a microfilm, a software or electronic device or any another means that is deemed appropriate.

Life of a facility: the period of time ranging from the design of the facility to the dismantling thereof.

Third. *Documents and records to be kept. Retention periods.*- The licensee of the nuclear facility must identify the documents and records related to the nuclear and radiological safety of the facility that must be filed, specifying their retention periods.

Nuclear facility documents and records will be classed as permanent and non- permanent.

Permanent documents and records will be kept for the entire life of the facility. Those corresponding to a structure or component must be kept for the entire life of the structure or component, including its storage time.

The documents and records needed for the dismantling of the facility as well as those generated during the dismantling documenting how said dismantling has been conducted and the final state of the facility will be kept until the declaration of decommissioning is obtained. Together with the declaration of decommissioning, the documents and record on the final state of the site will be placed at the CSN's disposal, this transfer of documentation being regulated in the same terms as those set in the Nuclear Safety Council's Instruction IS-04, of 5th February 2003, regulating the transfers, filing and safekeeping of documents related to radiological protection in nuclear power plants upon their dismantling and decommissioning.

Non-permanent documents and records will be kept for a period of time not shorter than five years.

Documents and records meeting one or more of the following criteria will be deemed permanent:

They document the design and construction of the nuclear facility.

They provide evidence on the nuclear facility having been tested and commissioned according to the design criteria.

They document the characteristics of the elements accepted for use in the nuclear facility, proving that the quality of the original equipment and spare parts meets the design specifications.

They document accepted elements and activities having nonconformities.

They prove the operating capacity of components as regards their relation to nuclear safety and radiological protection.

They contain information needed for carrying out equipment maintenance, repairs, replacements or modifications.

They contain information needed for conducting inspections or tests on structures, systems and components of the facility.

They prove that the maintenance of the plant is being performed according to the design requirements and the approved maintenance programme.

They contain information needed for properly training personnel so that they can perform their jobs.

They contain significant information to determine the cause of an accident or malfunction of a structure, system or component.

They confirm the reliability of the design on the basis of the plant's operating history.

They prove compliance with applicable regulations.

They prove that doses received by personnel and effluent discharges are within established limits.

They contain information needed for properly managing the nuclear substances and radioactive waste generated and/or managed at the facility.

They document the characterisation, treatment and storage of the nuclear substances and radioactive waste generated and/or managed at the facility.

They contain information needed for dismantling the facility.

They document the manner in which the facility has been dismantled and the final state of the site.

Appendix 17A-1 of Standard ASME-NQA-1-2008 "Guidance on Quality Assurance Records" is considered an acceptable guide for the identification of permanent documents and records.

Documents and records that, in spite of not meeting any of the previous criteria, are necessary so as to prove that the activities have been carried out according to the specified requirements will be deemed non-permanent.

Fourth. *Requirements on the documents and records to be kept.-* The documents and records to be kept will be original or duly authenticated copies.

The integrity, authenticity, non-repudiation, intelligibility, protection against alterations or falsifications and capacity of recovery and reproduction will be guaranteed throughout the entire period of retention of the documents and records to be kept.

The documents and records to be kept must remain readable, easily identifiable and recoverable. A documented procedure for defining the controls needed to identify, authenticate, store, protect and recover the records and the times of retention and availability thereof will be established.

When documents and records are in software or electronic form, it will be ensured that the capacity for the recovery, reading and reproduction thereof is maintained throughout their entire retention period. Appendix 17A-2 of Standard ASME-NQA-1-2008 "Guidance for Electronic Records" is considered an acceptable guide for the authentication, recording, storage, keeping and deletion of this type of documents and records.

Files where documents and records to be kept are saved must be generated and kept in accordance with those regulations guaranteeing the safety and proper conditions of conservation and recovery of the documents and records deposited in them. When necessary, duplicate files will be used.

In the event documents and records related to the nuclear and radiological safety of nuclear facilities generated by external engineering companies, service providers, inspection agencies and manufacturers cannot be transferred to facility licensees for industrial or intellectual property reasons, the latter, by being responsible for complying with this Instruction, must establish contractual agreements so that said documents and records are filed and kept by these external organisations under the conditions set in this Instruction and placed at the disposal of the proper Authorities when these so require it.

Once a nuclear facility obtains its dismantling permit, it will be ensured that the records of the operating organisation are properly transferred to the dismantling organisation. The deletion of records may only be carried out in a justified, controlled and documented manner.

Fifth. *Exemptions.-* The licensees of the nuclear facilities object of the present Instruction may request being exempted from observing any of its requirements, explanatorily justifying the reasons for their request and establishing an alternative manner in which the established requirements will be observed.

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 XIV (Articles 85 to 93) of Law 25/1964, of 29th April, on Nuclear Energy.

Sole Final Provision. *Entry into force.*

The present Instruction will come into force six months after it is published in the "Official State Gazette" so as to be able to correct during this time possible deviations with regard to that established in the present Instruction.

In Madrid, on the 19th of May of 2010.- Carmen Martínez Ten, the President of the Nuclear Safety Council.