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Regulatory Instructions and Guidance published by the CSN to overcome some difficulties to apply the regulatory requirements

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Abstract

The objective is to present three binding Safety Instructions (IS) and one Safety Guidance (GS) issued by the CSN in relation with the transport of radioactive material, which try to fill gaps in the regulatory requirements or help to its application.

The necessary training of workers involved in the transport of radioactive materials is not specify by the IAEA SSR- 6 and not sufficiently detailed by modal Regulations as the ADR, which applies to the road mode in the European Union (EU). The **CSN IS-38** develops the ADR requirements on training and specifies which personnel should receive training, the minimum content of such training, their frequency and the characteristics of the training records.

Neither SSR -6 nor modal Regulations establishes when a change on the package may involve a design modification that shall lead to the revision of its certificate of approval. The **CSN IS-35** defines the procedure to be followed by designers, manufacturers or users to analyze whether a modification has enough impact on safety and then involves a revision of the design approval certificate. This IS also applies to non-approval packages and defines the analysis to be carry out by the user or consignor in case they decide to perform a modification on the packaging.

The Regulations do not specify neither the structure nor the content of the documentation of compliance of regulatory requirements for non-approval packages (para. 801 of the SSR- 6). The **CSN IS-39** defines the structure of that document, which is in line with that defined by the Technical Guide on Package Design Safety Report of the European Association EACA, and also establishes the procedure for periodic control of the packages manufacture.

The SSG -33 IAEA Guide (Schedules) is a useful tool for helping to apply the requirements of SSR-6 Regulations; however, there is not a similar guidance referring to the modal regulations. The CSN has issued the **GS-6.5**, which has a similar goal of SSG-33 but focused on helping designers, manufacturers, consignors, carriers and consignees to compliance with the ADR.

Introduction

The IAEA SSR-6 establishes requirements for a safe transport of radioactive material, which are transferred to the modal international regulations on transport of dangerous goods: ADR, RID, ICAO Technical Instructions and IMDG Code. These regulations are applied in Spain through their national regulations.

Modal regulations, and even the IAEA SSR-6, are sometimes excessively general and then no very clear when they define some requirements, for example, on training of workers, modifications of package designs or content of the documentation to justify the compliance of regulations requirements for non-approval packages.

Regarding these potential improvements in the transport regulations, the Nuclear Safety Council (CSN) have issued in Spain some binding safety instructions called 'CSN Instructions' (IS), which try to specify as much as possible the requirements that the CSN has considered not enough clear or insufficiently developed by the transport modal regulations: IS-35 on the package design modifications procedure, IS-38 on training aspects and the IS-39 for the compliance documentation for non-approval packages.

On the other hand, taking into account that one of the most important responsibilities of competent authorities is to facilitate the application of regulations by users, the CSN is investing significant resources in developing an extent set of guidance documents. A good example of this policy is the Safety Guide GS 6.5 that help to apply the requirements established by the ADR for the transport of radioactive material by road.

The *Law 15/1980 on the creation of the Spanish Nuclear Safety Council* gives the CSN competences to develop and approve technical instructions and guides in the field of the nuclear and radioactive facilities and any other activity affecting nuclear safety and radiation protection, as the transport of radioactive material. The objective of this paper is to present three CSN Instructions and one CSN Safety Guide in relation with the transport of radioactive material, which try to fill gaps in the transport regulatory requirements or help to its application.

1. Process of package design modifications (CSN IS-35)

The Nuclear Safety Council Instruction IS-35 *on the treatment of modifications of packages designs requiring a certificate of approval of Spanish origin and on the treatment of physical modifications performed on the packaging or on the operational procedures of the package by the user*, was published in December of 2013 [1].

International regulations on transport of dangerous goods not specifically consider provisions on the procedure to be followed in the case of potential design modifications of packages subject to a design approval. That is, transport regulations do not respond to the question: Is it always necessary the revision of a certificate of approval, regardless of the type of modification intended to be done? Moreover, in addition to those design modifications coming from the designer, sometimes the users of packages may consider necessary to make some modification on the packaging to facilitate loading, handling or transport of packages. For this case, the question not answered by regulations is: May users of packages carry out some kind of modifications on the packaging or on its operation procedures?

Trying to solve both points, the CSN published the instruction IS-35 with two main objectives:

- Define the procedure to be followed by the designer to decide if a modification on a package implies a design modification that should lead to a revision of an approval certificate of Spanish origin.
- Define the procedure to be followed by the user of a package to decide if a potential modification on the packaging would imply a design modification that should lead to a revision of the approval certificate (approval packages) or the compliance documentation (non-approval packages).

For both cases, the CSN IS-35 defines a process with two stages: a *Preliminary Analysis* (PA) that shall answer the question: does the modification affect to the package safety?, and a second phase called *Safety Evaluation* (SE) to decide if that modification affecting potentially to safety really affects to design criteria, standards requirements or approval conditions. Figures 1 and 2 show the diagram of the process for both cases.

It is important to emphasize that for the case of potential modifications to be performed by users of packages, the CSN IS-35 requires an explicit supervision and acceptance by the package designer of the conclusion of the SE carried out by the user.

The CSN IS-35 also requires the PA and SE processes have to be documented by designer and users and the records be available to the CSN inspection. For the particular case of the approval packages modifications, the IS-35 requires the designer sends an annual report to the CSN of all the modifications no requiring a revision of the certificate of approval and defines the frequency this designer should issue a revision of the Package Design Safety Reports (PDSR) to include those modifications.

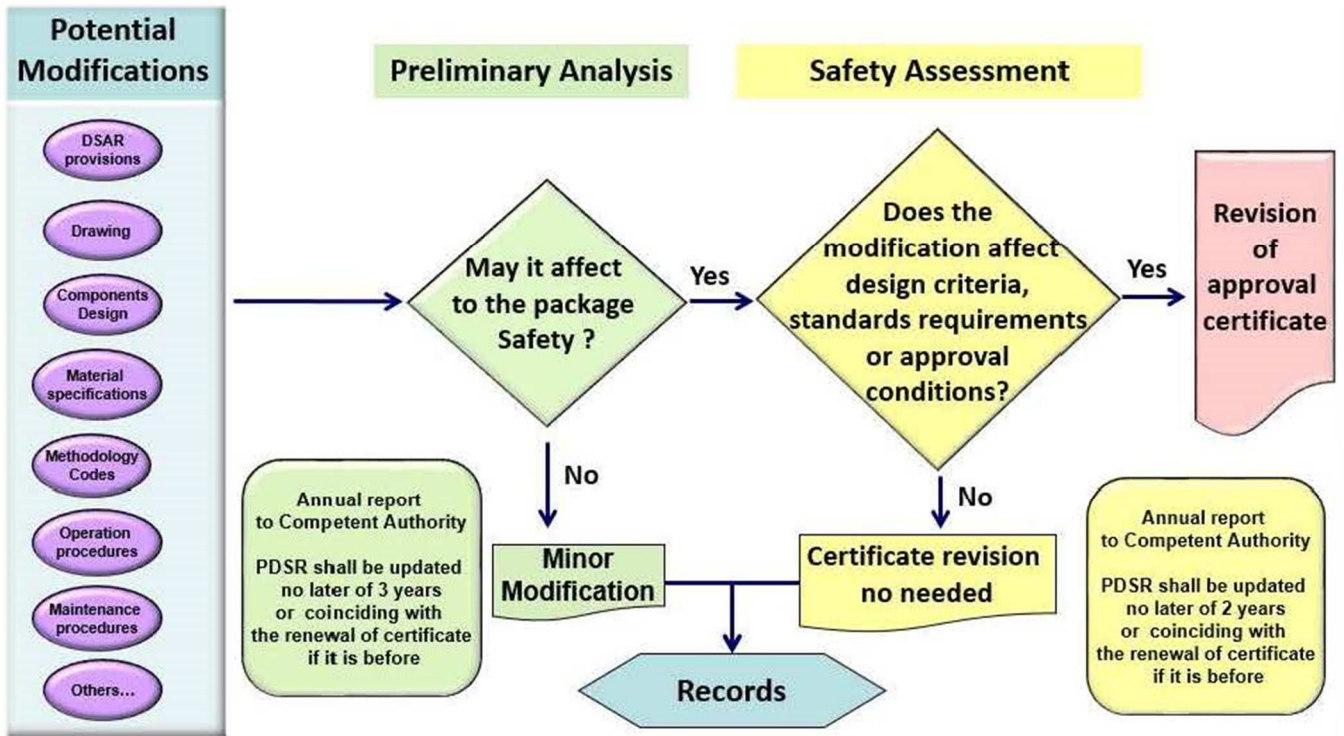


Figure 1. Process for design modifications on approval packages

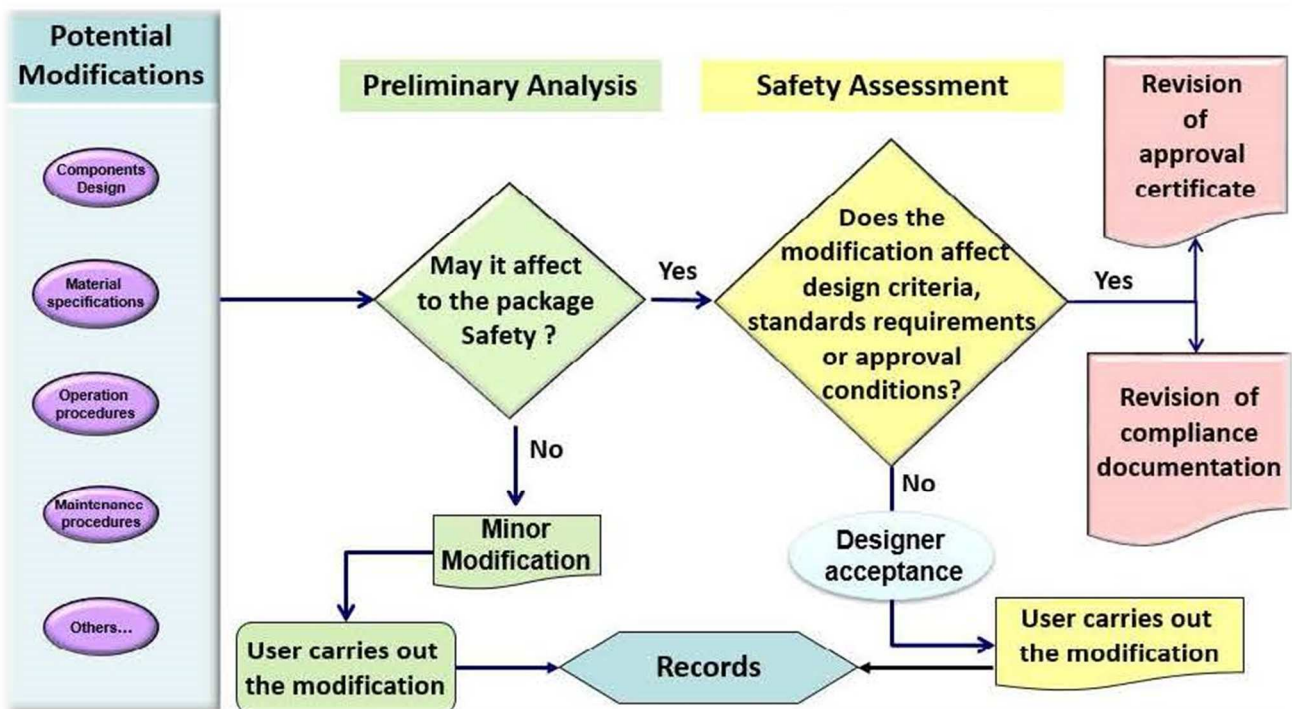


Figure 2. Process on potential modifications to be made by users on packaging

2. Training of transport workers (CSN IS-38)

The chapter 1.3 of ADR [5] includes provisions on the training of workers involved in the transport of dangerous goods by road in Europe. This training should include an initial training adapted to the tasks and responsibilities of workers and a periodic training to taking into account the changes of regulations. However, the ADR, except for the specific case of drivers (excluding drivers transporting UN 2915 and UN 3332 consignments) is not enough specific and detailed, especially for the periodic training.

In June of 2015 the CSN published the IS-38 *on the training of persons involved in the transport of radioactive material by road* [2], intending to solve the lacks of ADR on this respect. The main objective of the safety instruction is to harmonize the training programs of consignors, carriers and consignees for the road mode. To reach this main goal, the IS-38:

- Define the content of initial and periodic training.
- Define the specific training depending on the activities carried out by workers.
- Specify the frequency of the periodic training.
- Establish the requirements of the training records.

In relation with the initial training, it shall include:

- a) General awareness: Familiarization with the general provisions of regulations, delivered to all personnel intervening in activities affecting safety regardless of the specific task performed. This includes: information on the national and international regulations in force, fundamentals and objectives of the requirements, definitions, exemptions, multi-mode transport requirements, personnel training requirements, responsibilities of the different participants in the transport of radioactive material, transitional arrangements and security measures.
- b) Specific training: adapted to tasks of the personnel performing activities affecting safety, as shipping preparation, loading/unloading vehicles, driving of vehicles and reception of packages (See details in table 1).
- c) Training on safety: to inform workers on risks of radioactive material and radiation protection.

Regarding the periodic training, the CSN IS-38 specifies a frequency of 24 months and requires the next content:

- a) An overview of general knowledge, introducing changes might have taken place in the regulations during the period.
- b) An overview of specific and safety-related training considering:
 - Changes implemented in work procedures to take into account the changes in regulations.
 - Analysis of problems, deficiencies or deviations observed in the performance of the activity during the period and the corrective measures applied.
 - Analysis of events occurring with details of the lessons learned.

Table 1. Specific Training defined by the CSN IS-38 (initial training)

Topics	Personnel preparing packages (1)	Personnel loading/ unloading (2)	Drivers (3)	Personnel receiving packages (4)
General concepts regarding types of materials and packages	X	X	X	X
Content limits by package type	X			X
UN numbers and material description	X	X	X	X
Marking on packages	X	X	X	X
Levels of radiation and contamination on packages and vehicles	X		X	X
Concept and determination of Transport Index and Criticality Safety Index	X		X	X
Package category and labelling	X	X	X	X
Requirements prior to transport, authorisations and notifications	X			
Transport documentation	X		X	X
Stowage in vehicle		X	X	
Storage in transit			X	
Limits on contents per vehicle		X	X	
Vehicle and equipment requirements			X	
Placarding of vehicles			X	
Segregation of packages from persons and other dangerous goods	X	X	X	X
Surveillance of vehicles			X	
Tunnels restrictions	X		X	
Security provisions	X	X	X	X

- (1) This personnel includes those preparing the transport documentation, configuring the package, determining the IT and marking and labelling the package.
- (2) Personnel performing package loading and unloading operation in vehicles and containers.
- (3) Drivers of vehicles no requiring ADR training certificate (UN 2915 and UN 3332).
- (4) Personnel performing reception checks and opening packages.

The CSN IS-38 also requires that the Training Program be included or referenced in the Radiological Protection Program of consignors, carriers and consignees and shall be available to the competent authority whenever requested. Additionally, the IS-38 defines the content of the training records and the period to keep these records (36 months). The records shall be available for the employee, when requested, and for the competent authority.

3. Documentation of compliance for non-approval packages (CSN IS-39)

The paragraph 801 of the IAEA SSR-6 establishes that for package designs where a certificate of approval is not required, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements ('compliance documentation'). This requirement has been included in the modal regulations on transport of dangerous goods.

However, although the IAEA SSG-26 gives some recommendations about the possible content of the compliance documentation for non-approval packages, the international regulations do not specify it. The experience acquired by the CSN in the control and inspection processes shows that most of consignors do not know how to comply adequately with this requirement and the documentation often presented to the CSN was very variable and poor. In consequence, the CSN resolved to regulate this particular matter through the instruction IS-39 *regarding control and monitoring in the manufacturing of packages for the transport of radioactive material*, which was published in June of 2015 [3]. Although the main objective of this instruction was to define a procedure to control the manufacturing of packaging, as the fundamental reference for an adequate fabrication is the PDSR of the package (compliance documentation for the case of non-approval packages) the CSN considered important to specify in this safety instruction what should be the minimum content of the documentation required by para. 801 of the IAEA SSR-6.

According to the CSN IS-39, the compliance documentation shall contain the information required for an analysis of the design of the package from the point of view of nuclear safety and radiological protection, demonstrating compliance with each of the applicable requirements of the regulation on the transport of dangerous goods. This information will be at least the following, depending on the type of package:

- a) Basic administrative information (name of package design, designer, type of package, operational restrictions and transport mode restrictions, edition of the regulations used as a reference to demonstrate compliance).
- b) Specifications of acceptable contents.
- c) Specifications of packaging defining its design, including drawings.
- d) Package performance characteristics.
- e) List of the standards provisions on transport of dangerous goods applicable to the package design.
- f) Requirements for operation of the package.
- g) Requirements for package maintenance and periodic verification.
- h) Management system, including the quality assurance program.
- i) Basic illustration of the package.
- j) Technical analyses demonstrating the fulfilment of the standards requirements, as appropriate: structural analysis, thermal analysis, containment design analysis and external dose rate analysis.

This structure of the compliance documentation is totally based on that defined by the Technical Guide of the European Association of Competent Authorities for the Safe Transport of Radioactive Material (EACA): *Package Design Safety Reports for the transport of radioactive material* [6]. The compliance documentation may be issued by the consignor, based on the documentation provided by the designer, the manufacturer or the supplier of the packaging, or directly by the designer or manufacturer.

4. Guidance for the application of transport regulations (CSN GS 6.5)

In order to assist users of SSR-6 to apply the requirements for the transport of radioactive material, the IAEA published the Safety Guide SSG-33 (Schedules). The requirements for the transport of radioactive material are included in the modal regulations on transport of dangerous goods, together with requirements applying to the rest of dangerous materials, what adds difficulties for the implementation of requirements affecting specifically to the class seven material. Then, in line with the concept developed by the IAEA SSG-33, which is considered a good tool to facilitate the application of the SSR-6, the CSN published the Safety Guide GS 6.5 [4], but focused on the application of the ADR requirements.

The objectives of the CSN GS 6.5 are to facilitate the users of ADR (designers, manufactures, consigners, carriers, consignees, competent authorities) an easy access to the requirements, helping to classify the consignment (material and package) and guiding towards those ADR requirements that apply to a particular consignment. The use of the CSN GS 6.5 is summarized by the diagram in figure 3.

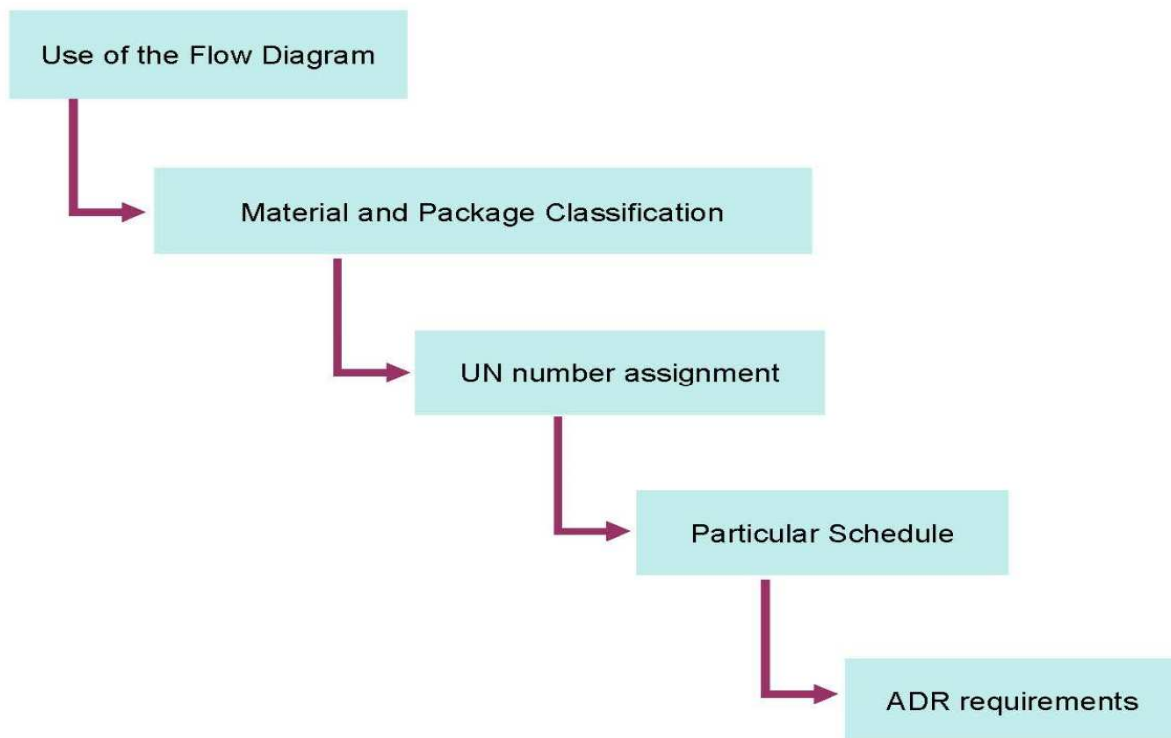


Figure 3. Process to determine ADR requirements according to CSN GS 6.5

The flow diagram or flow chart used in the GS 6.5 is similar to that included in the IAEA SSG-33 and helps to identify the UN number of a particular consignment. For each UN number there is a schedule, which has three columns: the paragraph of ADR where the requirement is established, the description of the requirements and an indication of what participant may be affected by the requirement (designer, manufacture, consignor, carrier or consignee).

The GS 6.5 is also supplied in electronic format, which permit a direct access to the ADR paragraphs through hyperlinks.

Conclusions

Modal regulations are sometimes excessively general and unclear defining some requirements. An example are the requirements on modifications of package designs, on training of workers or about the compliance documentation of non-approval packages. Trying to solve those lacks in regulations CSN has published the safety instructions IS-35, IS-38 and IS-39.

These safety instructions are generating significant improvements in the applications of transport regulations in Spain and leading to the harmonization of procedures applied by designers,

manufactures, consignors, carriers and consignees, which will help to the inspection activities of the competent authority.

Taking into account that one of the most important responsibilities of competent authorities is to facilitate the application of regulations by users, the CSN has also published the Safety Guide GS 6.5 that help users of ADR (designers, manufactures, consignors, carriers, consignees, competent authorities) to apply the requirements established by the ADR for the transport of radioactive material by road.

The Safety Guide GS 6.5 has permitted a good improvement in the use of transport regulations, since it facilitates the access to the regulations requirements and lead the users to a better compliance and consequently to improve the safety in the transport of radioactive material.

Access to the CSN Instructions and the Safety Guide 6.5 is possible through the web site: www.csn.es.

References

1. Nuclear Safety Council Instruction IS-35, of December 4th 2013, relating to the treatment of design modifications of radioactive material transport packages accompanied by certificates demonstrating their Spanish origin and of the physical or operational modifications performed by the consignor of a package on the packaging used. Official State Gazette n° 4, 4th January 2014.
2. Nuclear Safety Council Instruction IS-38, of June 10th 2015, on the training of persons involved in the transport of radioactive material by road. Official State Gazette n° 160, 6th July 2015.
3. Nuclear Safety Council Instruction IS-39, of June 10th 2015, regarding control and monitoring of the manufacturing of packages for the transport of radioactive material. Official State Gazette n° 160, 6th July 2015.
4. Nuclear Safety Council Safety Guide 6.5. Guide to facilitate the application of regulations requirements on transport of radioactive material (Updated to ADR 2015). CSN 2015.
5. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). 2015 edition. UNECE.
6. Technical Guide on Package Design Safety Reports for the transport of radioactive material. European PDSR Guide ISSUE 3 (December 2014). European Association of Competent Authorities for the Safe Transport of Radioactive Material (EACA).