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**Inspections programme of the Belgian competent authority (FANC) for non-approved
and approved package designs**

Thomas BANDE Marlon HESIUS Vincent LEBLANC Guy LOURTIE
Federal Agency for Nuclear Control, Brussels, Belgium

ABSTRACT

In January 2013, the FANC started a project to revise the Belgian legislation for the transport of radioactive material taking into account a large involvement of stakeholders of the sector [1]. The Royal Decree of 22 October 2017 on the transport of class 7 dangerous goods was published in the Belgian Official Journal on 30 October 2017 and came into force on 1 January 2018.

With this new Belgian legislation, the FANC established a notification system for Belgian non-approved package designs and for packagings conform to approved package designs that are used or stored (Dual Purpose Cask) in Belgium. This system enables the FANC to improve its compliance assurance programme.

Starting from January 2019, the FANC's inspections programme has also been reinforced. This inspections programme was previously consisting of:

- one-off inspections of shipments,
- management system inspections (compliance audits) of registered organizations (carriers, handling agents, ...),
- occasional inspections of non-approved package designs, and
- occasional packaging manufacture inspections.

Taking into account the graded approach, this inspections programme will be completed with a systematic inspections programme for (i) Belgian non-approved package designs and (ii) packagings conform to approved package designs that are used or stored (Dual Purpose Cask) in Belgium.

The paper will discuss the important aspects considered in the development of the extension of the FANC's inspections programme for non-approved and approved package designs and provide feedback on the first results.

INTRODUCTION

In January 2013, the Federal Agency for Nuclear Control (FANC) started a project to revise the Belgian legislation for the transport of radioactive material taking into account a large involvement of stakeholders of the sector [1].

The Royal Decree of 22 October 2017 on the transport of class 7 dangerous goods [2] was published in the Belgian Official Journal on 30 October 2017 and came into force on 1 January 2018, and 4 related FANC regulations of 13 December 2017 were published in the Belgian Official Journal on 18 May 2018.

The main goals and principles of this project and the new regulatory framework were to:

- a) simplify the licence system, by focusing on inspections and compliance audits;
- b) focus on continuous improvement;
- c) take into account the graded approach;
- d) take into account our knowledge and experience of transports of class 7 dangerous goods in Belgium;
- e) take into account the whole transport logistics chain;
- f) establish an involvement and participation of all stakeholders;
- g) optimize the organisation of the Import & Transport Section.

On the other hand, this project enabled (i) to clearly appoint the FANC as the competent authority for the different approvals foreseen in the international regulations for the safe transport of radioactive material [3] and for the follow-up of non-approved packages, including the manufacturing and maintenance of packages and (ii) to complete the FANC's inspections programme with a systematic inspections programme for Belgian non-approved package designs and for packagings conform to approved package designs.

STRUCTURE AND PRINCIPLES OF THE NEW LEGAL TEXTS

Royal Decree of 22 October 2017 on the transport of class 7 dangerous goods

The Royal Decree first summarizes the general provisions and subsequently sets forth the specific provisions for each stakeholders group. It is structured in 12 chapters with different sections to ensure the readability and functionality of the legal text.

The chapters of the Royal Decree relevant for the packages and packagings are:

- Chapter 7: Obligations for package design approval applicants;
- Chapter 8: Obligations for other approvals specified in chapter 7;
- Chapter 9: Various obligations for package design and packagings;
- Chapter 10: External advice.

FANC regulations on the transport of dangerous goods of class 7

The FANC issued 4 specific regulations to complement the Royal Decree and to specify some practical issues. One is related to the obligations for packages and packagings:

- FANC regulation concerning Chapters 7, 8 and 9 of the Royal Decree of 22 October 2017 on the transport of Class 7 dangerous goods [4].

Principles of the provisions of the new legal texts

In the Royal Decree, Chapter 7 – Obligations for package design approval applicants – is subdivided in 2 section. Section 7.1 deals with the initial application for the package design approval and stipulates who and how to apply, explains the principles of the review and

assessment and defines the form of the certificate: a certificate of approval or a certificate of validation. Section 7.2 is similar for the amendment or renewal of a certificate.

Chapter 8 is related to the obligations concerning approvals other than those in Chapter 7 of the Decree, for example the approval for special form of radioactive material.

Chapter 9 resumes miscellaneous provisions relating to package designs and packagings for the transport of Class 7 dangerous goods.

The obligations relating to the manufacture of packagings for the transport of Class 7 dangerous goods are provided in section 9.1.

Miscellaneous notifications to the FANC relating to package designs and packagings for the transport of Class 7 dangerous goods are resumed in section 9.2.

Chapter 10 – External advice – stipulates how and when the FANC can seek advice from an expert or the expertise of a national or international organisation (i) in the context of the manufacture or maintenance of packagings used for the transport of Class 7 dangerous goods and (ii) more generally, regarding all aspects of the transport of Class 7 dangerous goods referred to in this Royal Decree. The cost of this advice or expertise shall be borne respectively (i) by the applicant of the approval in Belgium or by the user of the packaging within the Belgian territory or (ii) by the natural or legal person who submits the application.

NOTIFICATIONS TO THE FANC RELATING TO PACKAGE DESIGNS AND PACKAGINGS

The notification system for the package designs and packagings put in place by the new Belgian legislation should (i) ensure that the FANC knows which packagings are transported and/or used (and by whom) on the Belgian territory and (ii) provide information to establish the triennial inspections programme and the yearly inspections plan.

Some notifications come from the international agreements and regulations governing the transport of dangerous goods, and others are specific for Belgium.

The forms to be used for the notifications, preferably submitted electronically, are attached to the FANC regulation concerning Chapters 7, 8 and 9 of the Royal Decree of 22 October 2017 on the transport of Class 7 dangerous goods.

The different notifications are hereunder summarized.

Manufacture of packaging notification

At least four weeks before the date on which the manufacturing of a packaging is due to start, the designer of:

- each package design where Belgium is the country of origin and where the design must be approved by the FANC,
- a package design that must be approved by the FANC and where Belgium is not the country of origin, and only for packagings complying with this design which are to be loaded in Belgium and will remain stored on Belgian territory for over one year, should notify the FANC.

The manufacturing planning and the manufacturing quality plans (MQP), also known as list of fabrication and controls (LOFC), should be attached to the notification.

Serial number notification (packagings manufactured in accordance with an approved package design).

The unique serial number of each packaging manufactured in accordance with an approved package design should be notified by:

- 1° the packaging owner in the case of a package design where Belgium is the country of origin;
- 2° the Belgian owner of the packaging in the case of a package design where Belgium is not the country of origin.

This notification shall be issued when:

- 1° a packaging is commissioned;
- 2° a packaging is decommissioned;
- 3° the owner of a packaging changes.

The certificate of conformity of the packaging should be attached to the notification.

Notification of first use of approved designs on Belgian territory

In the case of designs approved by the FANC, the first use of an approved package design or special form of radioactive material should be notified by:

- 1° the Belgian owner of the packaging or source, if applicable;
- 2° the Belgian consignor if the package is loaded on Belgian territory; or
- 3° the Belgian consignee in the absence of a Belgian owner or consignor.

The notification shall at the very least include the date on which loading of the packaging is due to start if this takes place on the premises of a Belgian consignor or the date on which the package or source is to be transported on Belgian territory.

In the case of approved package designs and special form of radioactive material, which have not been approved by the FANC, the notification shall be issued by the consignor.

The notification shall at the very least include a copy of the relevant approval certificate and shall specify the date of the first transport operation, which is due to take place on Belgian territory.

Notification of use of non-approved package designs (type IP-1, IP-2, IP-3 and A) on Belgian territory

Before the end of the first quarter of each year, the use of non-approved package designs on Belgian territory, with the exception of excepted package designs, should be notified by:

- 1° the designer of the package design if this designer is Belgian, or;
- 2° the Belgian owner of the packaging if the package designer is not Belgian, or;
- 3° the Belgian consignor if neither the designer nor the owner is Belgian, or;
- 4° the Belgian consignee if neither the designer, owner nor the consignor is Belgian.

The notification is not required for these packages if they are only in transit within Belgium.

The certificate of compliance of the package design (description of the packaging and allowed radioactive content, see para 801.3 of SSG-26 [5]) should be attached to the notification.

COMPLIANCE AND INSPECTIONS PROGRAMME

According to the FANC internal policy on inspections, an inspections programme and an inspections plan for the transport activities are established respectively triennially and yearly. Beside the inspections (one-off inspections or compliance audits) of the carriers or organisations involved in the multimodal transport and based on the notification system for package designs and packagings, the FANC has established a triennial inspections programme for the package designs, packagings and other approvals defined in the international agreements and regulations governing the transport of dangerous goods. The FANC inspections programme for the package designs and packagings also takes into account the graded approach principle.

In the current state, the FANC's inspections programme for non-approved and approved package designs has the following axes.

Approved package designs where Belgium is the country of origin

The manufacture of the first packaging complying with a Belgian package design is systematically inspected.

The FANC will first realise a management system inspection (compliance audit) of the manufacturer to ensure that the manufacturer has implemented a management system for assuring compliance with the requirements of the designer and the safety analysis report.

Based on the manufacturing quality plans (MQP), FANC will define witness and hold points for which the designer/manufacturer should notify the FANC before the operation. The FANC will assess if the inspector in charge will attend the operation or not.

For mass production, the FANC will periodically inspect the manufacturing of packagings:

- one packaging's manufacturing in three for packagings containing fissile material which are to be loaded in Belgium and will remain stored on Belgian territory for over one year, typically dual purpose casks;
- one packaging's manufacturing in six for other packagings containing fissile material;
- one packaging's manufacturing in ten for other packagings.

The first use and the first maintenance operations on Belgian territory of these packagings will be systematically inspected.

Approved package designs where Belgium is not the country of origin, with a Belgian owner

For packagings complying with a package design containing fissile material, which is to be loaded in Belgium and will remain stored on Belgian territory for over one year, typically dual-purpose casks, the FANC has the same approach as for the Belgian package designs for the inspection of the first manufacture and the management system inspection of the manufacturer.

For mass production, the FANC will periodically inspect the manufacturing of packagings:

- one packaging's manufacturing in six for packagings containing fissile material which are to be loaded in Belgium and will remain stored on Belgian territory for over one year, typically dual purpose casks;
- one packaging's manufacturing in ten for other packagings containing fissile material;
- one packaging's manufacturing in twenty for other packagings.

The first use and the first maintenance operations on Belgian territory of these packagings will be systematically inspected.

Non-approved package designs (type IP-1, IP-2, IP-3 and A)

The FANC will review the safety analysis report of non-approved package designs used on Belgian territory: one by quarter. The inspected non-approved package designs are yearly selected based on the received notifications and criteria such as the country of origin or the widespread use (the Belgian designs and the most used packagings on Belgian territory are inspected first).

The inspection report will be sent to the Belgian stakeholder (designer or owner or consignor or consignee).

Other approvals

Other inspections can be planned, such as inspections of a shipment under special arrangement, inspections of manufacturing of special form of radioactive material,...

FEEDBACK AND LESSONS LEARNED

Non-approved package designs

The notification system for the package designs and packagings is new and the FANC received by end March 2019 the first notifications of non-approved package designs.

It enables the FANC to have a better view on which non-approved package designs are used on Belgian territory and by whom.

We already reviewed two safety analysis reports of non-approved package designs.

No fundamental issues for the safety of the package design were found. Nevertheless, there are necessary improvements for the documentation, justifications and the certificate of compliance. The guidance (PDSR guide) issued by the European Association of Competent Authorities for the Safe Transport of Radioactive Material [6] and its future international version being finalized within IAEA are highly recommended by the FANC to the stakeholder as assistance for justifying that the package design meets the applicable requirements of the dangerous goods transport regulations.

Approved package designs and other approvals

In the past, the FANC already inspected activities related to package designs and packagings, such as package designs where Belgium is the country of origin or approved package design containing fissile material used or stored (Dual Purpose Cask) in Belgium.

These inspections were occasionally planned without a systematic and graded approach.

The criteria to establish the FANC's triennial inspections programme and yearly inspections plan are now independent, more clear and understandable for the designer, manufacturer or user. We expect that the stakeholders will appreciate and recognize this transparent and clear approach.

CONCLUSIONS

By completing the FANC's inspections programme with a systematic inspections programme for the package designs and packagings, we expect to improve the compliance assurance that a competent authority should put in place to ensure that the requirements of the national and international regulations for the safe transport of radioactive material are met in practice (see para 307 of SSR-6 [3]).

This systematic inspections programme and the resulting yearly inspections plan for the package designs and packagings fit also with (i) the preventive versus repressive approach promoted by the FANC and (ii) the identification and sharing of best practices among all stakeholders.

It is also a way to better communicate to the public how the inspections of the FANC are planned independently.

ACKNOWLEDGMENTS

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