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Alternative activity limits for exempt consignments in Belgium – Feedback and lessons learned

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Abstract

The 2012 Edition of the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) [1] has introduced the concept of alternative activity limit for an exempt consignment of instruments or articles, which requires multilateral approval by the competent authorities involved. These requirements have been transposed into the latest edition of the modal regulations (ADR, RID, ADN, ICAO TI, IMDG). Applicants and authorities from several countries are therefore currently dealing with applications for this new type of approval.

On the other hand, European Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation [2] requires that the use of radioactive substances in consumer products be justified and subject to licensing by the competent authority. These requirements have been transposed into Belgian regulations [5].

For consumer products that are used in Belgium, both regulations apply. The Belgian competent authority (Federal Agency for Nuclear Control, FANC) has set up a joint expert group to deal with the consumer product licence. In order to facilitate the regulatory process, applications for the approval of an alternative consignment exemption limit are simultaneously reviewed by the joint expert group on the basis of a single application submitted through the consumer product licensing framework.

In 2015, the FANC received applications for the approval of an alternative activity limit for an exempt consignment of lamps containing Kr-85 or Th-232. Difficulties and recurring misunderstandings between the FANC and the applicants, but also good practices have been identified during the review of these applications.

This paper discusses the FANC's feedback on the joint expert group from the transport's perspective and the lessons learned regarding the approval of an alternative activity limit for an exempt consignment.

Introduction

Radioactive material added in goods for various reasons exists and is currently available. In order to avoid excessive exposure to ionizing radiation resulting from the manufacture, transport, storage, use and disposal of such goods, the IAEA safety standards (particularly the BSS [3]) have provided the basic requirements for regulatory control of such goods while also including provisions for the exemption of low risk practices from excessive regulatory control.

For the transport of such goods, besides the exemptions already applicable for radioactive material in approved consumer goods that have received regulatory approval following their sale to the end user, the 2012 Edition of the IAEA Regulations for the Safe Transport of Radioactive Material SSR-6 [1] has introduced the concept of an alternative activity limit for an exempt consignment of instruments or articles, subject to multilateral approval by the competent authorities involved. This new concept has been deemed necessary to address shipments to (and storage in) warehouses of large numbers of items for which radiological risks are sufficiently low and regulatory control yields only little benefit.

In Belgium, the implementation and application of the concept of alternative activity limits for exempt consignments started in 2015.

Regulations in Belgium

Consumer goods regulation

Until 2014, the addition and use of radioactive material in consumer goods was formally not allowed in Belgium except in licensed facilities. This ban was contradictory to the provisions of the BSS [3] and European Council Directive 96/29/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation [4]. Given the free movement of goods and the well-established practice within the European Community, this ban was not fully complied with and not sustainable.

In 2014, the notion of and requirements related to consumer products defined as : “A device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale” entered into force in Belgium following the transposition of European Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation [2] into Belgian regulations [5].

The principles of the Belgian regulations on consumer goods are :

- The addition of radioactive material to consumer goods remains prohibited unless authorized by the FANC, and provided that the following conditions are met :
    - the addition of radioactive material is a justified practice (justification principle);
    - the radiological criteria (public and worker exposition) for exemption of the practice

are fulfilled;

- The holding of consumer products could be exempted of additional licences [a];
- In this case, the transport of these consumer products is allowed without any further regulatory control.

Transport regulation

Through the Belgian regulations [6], the different modal regulations for the transport of dangerous goods (ADR, RID, ADN, ICAO TI, IMDG) apply on Belgian territory. The latest edition of these modal regulations transposing the prescriptions of SSR-6 [1] includes the already existing exemption for radioactive material in consumer products that have received regulatory approval, following their sale to end user (para. 107. (e)) and the new concept of alternative activity limits for exempt consignments (para. 403(b)).

According to these regulations, multilateral approval is required for these alternative limits and the contents of an application for such approvals are described in para. 817 of SSR-6 [1].

Pathways for being exempted from regulatory control

According to the provisions of the different regulations, all transports of consumer goods into which radioactive material has deliberately been incorporated or produced by activation on Belgian territory may be exempted from regulatory control in many different ways, depending on the activity and use of these goods.

If the consumer goods are not used or held on Belgian territory (i.e. transit only is considered) and if the applicable activity limit concentration and the activity limit for exempt consignment are exceeded, only an application for the approval of an alternative activity limit for exempt consignments should be introduced.

If the consumer goods are also available on the Belgian market, an application to exempt the holders and users of additional licences should be introduced. In this case, the modal regulations are also applicable. If the activity concentration limit and the activity limit for exempt consignment are exceeded, an approval for an alternative activity limit for exempt consignments should also be obtained. For these cases, the FANC has published a guideline [7] about how a single application for exemption from authorization for consumer goods containing radioactive material should be introduced in order to simplify the administrative burden for the applicant. The authorization will thus include the approval of the alternative activity limits for exempt consignments if needed.

Of course, if the activity concentration limit or the activity limit for exempt consignments is not exceeded, transport regulations do not apply.

[a] According to the definition of consumer products, there are no more additional licences required after the sale to the end user. However, it seems likely that some holders of such goods (i.e. other parties in the supply chain like shops, intermediate logistics centres, importers,…) should in theory obtain additional licences due to the accumulation of large quantities of consumer products.

Applications for alternative activity limits for exempt consignments

Guideline

In Belgium, almost all possible applications for alternative activity limits for exempt consignments should be introduced through the consumer product licensing framework [b]. The guideline [7] contains a form which can be used to soften the administrative burden of the applicant to provide the acceptable justifications and the information needed to get an exemption from additional licences.

The form contains the following items with further explanation :

i. Identification of the applicant;
ii. Identification and detailed description of the consumer goods (per type) :
    a. Application (use, technical sheet, target group,…);
    b. Radioactive material (radionuclide(s), activity, physical and chemical form, sealing,…);
    c. Radiation levels (per good, per package and per overpack);
    d. Details about the manufacture and design;
    e. Lifetime and estimated number of items distributed per year;
iii. Safety analysis including dose assessments in accordance with the principles and methodologies set out in the BSS [2] under routine and accident conditions, during storage (including as waste) and under potential misuse;
iv. Benefits (and disadvantages) of the incorporation of the radioactive material in the consumer goods (reason, technical and scientific function of the incorporated radioactive material, benchmark studies comparing these consumer goods with goods without incorporated radioactive material);
v. Justification for incorporation of radioactive material in consumer goods (justification principle);
vi. Transport conditions:
    a. alternative activity limits for exempt consignments;
    b. maximum number of goods per shipment;
vii. User information (manual, use, maintenance, waste management, marking,…);
viii. Risk of malicious use (security);
ix. Management System (to ensure that the maximum specified activity and radiation levels are not exceeded).

These items cover among others all the information required in para. 817 of SSR-6 [1] describing the information which shall be included in an application for approval of alternative activity limits for exempt consignments.

[b] A single application for an alternative activity limit of exempt consignments could only be introduced for consumer goods containing radioactive material which have been authorised in other countries but not in Belgium.

Applications submitted to and assessed by the FANC

In 2015, three lamp manufacturing companies and the industry association of the lighting company applied, for the first time in Belgium, for higher activity limits for exempt consignments of lamps containing Kr-85 or Th-232. These lamps have been used in various applications in public or professional environments (entertainment (projection beam), automotive (headlamps), high ceiling buildings,…).

Kr-85 provides the starter aid function for the ignition of the lamp by supplying free electrons. Th-232 is incorporated in the electrode to improve its properties and to increase stability of the electric arc between the electrodes.

Since these lamps are used, sold, stored and transport on Belgian territory, the applicants stated that these lamps should be considered as consumer products and therefore also requested an exemption from additional licences. Hence, the applications were processed in the consumer product licensing framework for which Guide [7] is intended.

Review of applications

These applications are reviewed and assessed by a joint expert group. This group has been set up to provide the technical knowledge that is necessary to assess the various radiological risks of the consumer products and it also seemed a good option to avoid that the judgement on the justification of the practice would reflect on a personal view. Currently, the joint expert group is composed of 9 members from different FANC Sections:

- 3 experts from the Surveillance of the Territory and Natural Radiation Section;
- 1 expert from the Import & Transport Section;
- 1 expert from the Industrial Facilities Section;
- 1 expert from the Health Protection Section;
- 1 senior expert from the Support Department;
- 1 person from the Support & Logistic Department (without expertise in radioactive material);

On top of the traditional steps for the review and assessment of an application by the FANC (such as the check of admissibility, the acknowledgment of receipt, the check of completeness and the assessment of the provided information), the advice of the Superior Health Council (SHC) is required but not binding. The SHC is an advisory body under the Federal Public Service of Health, Food Chain Safety and Environment that draws up scientific advisory reports providing guidance to political decision-makers and health professionals in order to guarantee and enhance public health.

During the review of the applications received in 2015, the following notable events occurred :

- The application from the association of the lighting companies has been considered as non-admissible given the absence of a clear identification and description of the design of the lamps. It was advised to the association deputy that each lamp manufacturing company introduces an independent application.

- An applicant withdrew its application arguing that Kr-85 would no longer be incorporated in its lamps given the success of a research and development project.
- Requests for additional information and answers to these requests have been exchanged several times between the FANC and the applicants. These requests mainly dealt with :
    - Detailed lamp specifications;
    - Management system;
    - Clear specification of the maximal activity per lamp and the alternative exemption limit;
    - Discrepancies between lamp specifications and assumptions in the radiological impact study.

Highlighted experience

The review of these applications highlighted some common problems but also some good practices.

- Firstly, there have been many recurring misunderstandings between the applicants and the FANC. Some concepts used in the transport of radioactive material such as *consignment, irradiation level,* or *alternative activity limit for exempt consignment* did not seem to be correctly understood by the applicants. On the other hand, the sector-specific terminology, acronyms and technical constraints were not easily understandable for the FANC.

  Improvements in guidance with clear explanation on the form, work in a partnership approach with each other and advice from consultants have been identified as possible solutions to avoid or mitigate misunderstandings.
- Secondly, it clearly proved to be quite a challenge for the applicant when asked to provide complete identification and detailed description of the consumer good because there is such great diversity in model, size and possible application with these lamps.
- The third topic is related to the radiological impact studies. The four applications all referred to a generic radiological impact study [8]. This was identified as a good practice, saving time for both the applicant and the competent authority.

  However, the use of a generic radiological impact study needs to be carefully coupled with the justification that the assumptions made in the study are conservatively representative for the specifications of the products. When processing the applications for the lamps, it appeared that justification about the assumptions related to the width and type of material providing shielding, volume of individual lamps and packing of lamps, maximal activity per lamp and real transport scenarios were often missing or incomplete.

  Obviously, it is connected with the description challenge : a generic application with no detailed description (including the specification such as minimum and maximum value over the product range) would lead to an awkward position both for the applicant – when making and justifying the necessary assumptions in the radiological impact study - and the competent authorities - when assessing the assumptions made.

- The fourth topic concerns the management system. Every application contained information about the management system in place, including quality assurance program to guarantee product quality, running and design tests and certificate of conformity to ISO-norm and other relevant standards. Although this information was sufficiently convincing to conclude that the lamps are manufactured in compliance with the general design specifications, none of this documentation provided information about the measures to be taken to ensure that the maximum specified activity of the radioactive material in the lamps is not exceeded.

  Once again, improvement in guidance with clear explanation about what information on management system is expected by the competent authority could easily avoid the occurrence of such shortcomings.
- The last topic is related to the justification principle for consumer products. The information needed to assess the justification of a consumer product as a practice is the most important part of the Belgian licensing framework for consumer products. As a rule, the practice of transport is justified when the use of the consumer products containing radioactive material is justified, i.e. when the expected benefits to individuals and to society from introducing or continuing to incorporate radioactive material in this consumer product outweigh the harm resulting from this practice.

  Although the practice of adding radioactive material to lamps seems justified worldwide, the applicants faced difficulties in providing information beyond the generalities presented in IAEA TECDOC 1679 [9]. The benefits were initially not quantified or compared with other practices in terms of ignition speed, lighting level, energy consumption or expected lifetime of the lamps.

  This information could be considered by the applicant as sensitive R&D or commercial information, or could be unavailable at the time of the application. However, working in a partnership approach with each other could facilitate documenting the evidence of the benefits at an early stage and before the product is available on the market.

  It should also be noted that the ongoing development of LED or other technical improvements lead to non-radioactive alternatives for some specific applications. Therefore, the justification of adding radioactive material to the consumer products should recurrently be reassessed as provided in IAEA safety guide [10].

Conclusions

The review of the first applications submitted in Belgium for the approval of alternative activity limits for exempt consignments of lamps containing Kr-85 or Th-232 have brought to light that processing these applications jointly with other licensing processes related to consumer goods facilitates the regulatory processes both for the applicants and the competent authority.

The assessment of the information provided with the applications has highlighted the necessity of clear and understandable guidance about the competent authorities' expectations as well as working

in a partnership approach with each other before launching consumer goods containing radioactive material on the market. It is particularly relevant to provide all necessary information to justify the practice and exempt the consumer goods from any additional licence when the radiation risks are sufficiently low and the regulatory control yields little benefit.

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