

**Assessment of Quality Assurance Measures for Radioactive Material Transport Packages
not Requiring Competent Authority Design Approval – 13282**

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ABSTRACT

The majority of transports of radioactive materials are carried out in packages which don't need a package design approval by a competent authority. Low-active radioactive materials are transported in such packages e.g. in the medical and pharmaceutical industry and in the nuclear industry as well. Decommissioning of NPP's leads to a strong demand for packages to transport low and middle active radioactive waste. According to IAEA regulations the "non-competent authority approved package types" are the Excepted Packages and the Industrial Packages of Type IP-1, IP-2 and IP-3 and packages of Type A. For these types of packages an assessment by the competent authority is required for the quality assurance measures for the design, manufacture, testing, documentation, use, maintenance and inspection (IAEA SSR 6, § 306). In general a compliance audit of the manufacturer of the packaging is required during this assessment procedure.

Their regulatory level in the IAEA regulations is not comparable with the "regulatory density" for packages requiring competent authority package design approval. Practices in different countries lead to different approaches within the assessment of the quality assurance measures in the management system as well as in the quality assurance program of a special package design. To use the package or packaging in a safe manner and in compliance with the regulations a management system for each phase of the life of the package or packaging is necessary. The relevant IAEA-SSR6 § 801 requires documentary verification by the consignor concerning package compliance with the requirements.

INTRODUCTION

For packages which don't require a competent authority design approval according the regulations [1] it is important to distinguish between the manufacturer of the packaging and the user of the packaging who loads it and, as consignor, provides it as a package for transportation. Depending on responsible acting persons, the regulations give different obligations. The manufacturer of the packaging has to design and manufacture according to IAEA regulations by using a competent authority approved management system based on national and international standards. The user/consignor of the package needs to possess documents for a safe operation of the packaging and for its maintenance and periodic inspections. These documents must be provided by the manufacturer. A lot of problems can occur at this interface, especially in globalized markets. Thus different questions are important:

- What are the packaging manufacturer obligations?
- What are the package user/consignor's obligations?
- What are the problems at the interface of the responsibilities?
- General problems for competent authorities, packaging manufacturer and package consignor.

PACKAGE TYPES AND COMPETENT AUTHORITY RESPONSIBILITIES

In principle two different cases are to be distinguished according to the regulations [1]:

1. packagings requiring a competent authority package design approval and
2. packagings not requiring a competent authority package design approval.

Category 1 includes Excepted Packages, i.e. for clinical reagents, Industrial Packages of Type IP-1, IP-2 or IP-3, i.e. containers and barrels for low level radioactive waste or Type A packages, i.e. for pharmaceutical products.

Category 2 includes Type B packages, i.e. for spent fuel elements or high level radioactive waste or radiation sources, Type C packages, i.e. for air transportation beyond a certain activity.

Within category 1 excepted packages and Type IP-1 packages do not need a competent authority approval for the management system whereas Type IP-2, Type IP-3 and Type A packages require a competent authority approval for the management system. That means for these packagings a management system for design, manufacture, testing, documentation, use, maintenance and inspection of the package is required.



Fig. 1. Steel sheet containers for disposal of radioactive waste (LLW) in Germany KONRAD repository (Picture: Eisenwerk Bassum)

All dangerous goods transport requirements for packages for the transport of radioactive material are based on the recommendations of the IAEA regulations. These regulations were translated into international standards regarding the transport of dangerous goods (ADR, RID, IATA-DGR, IMDG-Code) as well as into national standards.

In excepted packages, in industrial packages and packages of Type A may only limited quantities, of radioactive material are transported. The limitation value is here the A2 value, which depends on specific isotopes. According to these limitations of the radioactive materials inside the package, an accident, which causes radioactive material release, does not lead to an inadmissible impact due to ionizing radiation. For these package types the package design type testing, in comparison with packages requiring a competent authority design approval, is rather “simple”. The test conditions cover only the routine conditions of transport respectively normal conditions of transport.



Fig. 2. Packaging drop test (LLW container at BAM Test Site Technical Safety)

The Federal Institute for Materials Research and Testing (BAM) is the German competent authority for the assessment and supervision of the management system for such packages. This competence is defined in the national standard and based on the paragraph §306 of the IAEA-regulations [1]. The management system includes each phase of the life of the package or the packaging such as the design, manufacture, testing, documentation, use, maintenance and inspection. In difference to packages, which require a package design assessment by the authorities and a subsequent package design approval, the competent authority is here only responsible for the assessment and supervision of a specific management system.

PACKAGING MANUFACTURER AND PACKAGE USER/CONSIGNOR

The distinction between the manufacturer of the packaging and the user of the packaging who loads it and, as consignor, provides it as a package for transportation is important. Depending on responsible acting persons the regulations give different obligations.

The responsibility of the manufacturer is defined in IAEA recommendations §306 [1]. So he has to provide and apply a competent authority approved management system.

The user/consignor of a package must be able to provide, on request of the competent authority, all documents and records, which show the compliance of the package with all applicable requirements. Competent authorities regarding this paragraph are the authorities, which are responsible for the supervision of the transport over public traffic routes.



Fig. 3. Transport of a package - LLW container on road vehicle (Picture: GNS)

After reading these paragraphs and the different defined responsibilities it is clear that different interpretations about the appropriate assignment of the obligations by the manufacturer, the user/consignor as well as the competent authority are obvious.

An additional guideline was established in Germany to support the responsible acting parties. Here the general formulation of the IAEA- recommendations are described more detailed.

MANUFACTURER OBLIGATIONS

The packaging manufacturer is responsible for the quality assurance measures for the design, manufacture, testing, documentation, use, maintenance and inspection [1] of a packaging respectively package. These quality assurance measures have to be described in a detailed quality assurance programme (Table 1), which is specified to each package design. The responsibility for compliance with these quality assurance measures lies solely with the manufacturer. In the course of design and construction of a packaging it must be shown the compliance with the regulations. This has to be done in terms of a package design safety assessment. The package design safety assessment and whose documentation lies in the direct responsibility of the producer.

The practice shows, that producers of such packagings have mostly no experience or knowledge with the regulation requirements for packages for the transport of radioactive material. However, this knowledge is essential to obtain. If the package design safety assessment is positive the producer has to be certified this in the form of a certificate for compliance with the regulations.

TABLE 1. Quality assurance measures by the manufacturer

Management System	Quality assurance program
System-related measures	Design-related measures
<ul style="list-style-type: none"> - Organization of operating processes - Competence/Responsibilities - Technological requirements - Organization, Qualification, internal audits - Cooperation of development, manufacture, quality control and operation of products (e.g. feedback, maintenance) - Cooperation with authorities and experts 	<ul style="list-style-type: none"> - External production control - Design and development, radioactive content - Sourcing of materials/components, package manufacturing - Quality control, deviation control, signing off documents, contents of documents - Experts certificate of confirmation - Use and maintenance documents, periodic inspections - List of documents for handover to the user - Producers certificate of design compliance with the regulations

The manufacture of the packaging is carried out according to a fabrication and test sequence plan which includes related working and testing instructions. In this plan each separate step of packaging manufacturing is described. Furthermore the corresponding design-related documents are mentioned here. These documents are e.g. design drawings, welding plans, manufacture instructions, but also applicable standards. The fabrication and test sequence plan also includes quality checks needed for the acceptance and documentation of the quality assurance measures e.g. measurement and test reports.

The producer has to prepare a complete documentation after the completion of the manufacture process of the packaging. This documentation includes specifications, qualification certificates and test results in the field of design, development, manufacture and acceptance, which characterize the quality of the packaging. Furthermore the producer has to provide packaging documents for operation, maintenance and inspections. These are binding documents for the user of the packaging. A handling- and maintenance instruction document (e.g. periodic inspection plans, handling procedures) is needed for an intended use and maintenance of the packaging. The producer is obliged to hand over these documents to the user of the packaging.

USER/CONSIGNOR OBLIGATIONS

The package consignor respectively the packaging user is responsible for compliance with the radioactive inventory limit and the permissible dose rate and surface contamination limits, and he is responsible for implementing the quality assurance measures during the operation of a

packaging. On the one hand the packaging manufacturer has the responsibility to establish and to hand over the required documents to the user, and on the other hand the user of the package has the responsibility to make sure to obtain these documents from the producer.



Fig. 4. A barrel for transport of radioactive material (Picture: Eisenwerk Bassum)

The user needs these documents, according to the regulations [1], to show the compliance of the package with all applicable requirements - on request of the competent authority.

These documents include the competent authority acceptance certificate of the quality assurance measures, the producer's certificate for package design safety assessment and its compliance with the regulations, the manufacture certificate, use and maintenance instructions (e.g. operation and handling instructions, periodic inspection plans, deviation measures, replacement of components, type and extent of documentation). Experience has shown that there are large implementation and interface problems. The consignor of the packaging, who provides it as a package for transportation, often does not know which documentation is required in terms of the package design safety assessment and the compliance of the package design with the relevant regulations. In addition there may still be any uncertainties of the competent supervisory authority. The competent authority according to regulations of paragraph 306 is e.g. not responsible for the transport regulations compliance.

What the producer of a packaging must do to get an approval of the quality assurance measures to manufacture a package not requiring competent authority design approval?

According to the regulation paragraph 306 [1] the competent authority is only responsible for the approval of the management system and has to assess the quality assurance program for a specific package design provided by the producer.

The competent authority has to supervise the manufacture process in terms of compliance of quality assurance measures with the requirements according to the quality assurance program. The work of supervision can also be done by an external expert working for the authority. An audit will be performed by the authority or an external expert as part of the approval process of the management system. The goal of the audit is to verify whether the quality assurance measures defined in the quality assurance program are suitable for use in the manufacture process and to check the boundary conditions for their implementation.



Fig. 5. A container for transport of radioactive material (Picture: Eisenwerk Bassum)

After a positive result of the assessment of the system-related and the design-related management system (defined in the quality assurance program) including the audit, the competent authority issues an acceptance certificate of the management system, and confirms that the manufacturer is able to manufacture a packaging with the required quality. This approval certificate is valid for a limited time. If necessary the producer has at the right time before expire date of the current acceptance certificate to make an application for a renewal.

It is recommended for the producer to make a technical discussion with the competent authority just before submitting the required quality assurance documents to the authority. The goal is to find a bilateral agreement between the applicant and the competent authority about type and scope of needed documents.

PROBLEMS FOR COMPETENT AUTHORITY, MANUFACTURER, USER

In the course of globalization packagings for the transport of radioactive materials, not requiring a competent authority design approval, are offered on the world market. Thus, in different countries packagings are used, which produced in other countries. Nevertheless, the requirement for an approved management system for the design, manufacture and operation of a packaging according to IAEA regulation paragraph 306 has to be fulfilled in each country of packaging origin.

Therefore there should be no differences at the requirements and the acceptance procedure of the management systems of the respective competent authority of a country. But the practice shows, that the requirements on a management system control are different in each country. This is understandable, because the paragraph 306 leaves room for interpretation by each country.

However, the fact is, that each used packaging needs an approved management system by the competent authority of country of origin. This approval has to be handed over to the user of the packaging because he must be able, according to IAEA paragraph 801, to show the compliance of the package including the packaging with the requirements.

CONCLUSIONS

The majority of transports of radioactive materials are carried out in packages which don't need a package design approval of a competent authority. The regulatory level in the IAEA regulations for these package types is not comparable with the regulatory density for packages requiring competent authority design approval. Therefore, any packaging manufacturer and any user of such packagings for transportation of radioactive materials (the package consignor) have the responsibility for regulatory compliance, the technical safety of the package and the protection of people and environment.

According to IAEA SSR-6, paragraph 306, a management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities (design, manufacture, testing, documentation, use, maintenance, inspection) within the scope of the regulations. For the purpose of this requirement, the competent authority of the country of origin of the packaging is responsible for approval of this management system, and to issue a competent authority acceptance certificate. In contrast to packages requiring a competent authority design approval these packagings can also be used in other countries without a re-validation of the responsible competent authority in that country. With respect to this situation there is a strong demand to harmonize both, the requirements on a management system and the assessment criteria of the competent authorities in the relevant countries.

REFERENCES

1. International Atomic Energy Agency (IAEA), Regulations for the Safe Transport of Radioactive Material, 2012 Edition, Specific Safety Requirements No. SSR-6, Vienna, 2012