Proceedings of the 19th International Symposium on the Packaging and Transportation of Radioactive Materials
PATRAM 2019
August 4-9, 2019, New Orleans, LA, USA

1128

REQUIREMENTS FOR MANAGEMENT SYSTEMS FOR MANUFACTURING OF TRANSPORT PACKAGES: THE NEW REVISION OF BAM-GGR 011 GUIDELINE

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Abstract

In accordance with IAEA SSR-6 para 306 a management system shall be established and implemented to ensure compliance with the relevant provisions of the IAEA regulations. BAM has issued an update of the guideline: the BAM-GGR 011. The new revision describes necessary quality assurance measures for design, manufacture, testing, documentation, use, maintenance and inspection of packagings for package designs requiring competent authority approval for the transport of radioactive material.
The measures can be categorised as system-related and design-related. They are independently approved and monitored by the German competent authority BAM and its authorised expert (BAM/T). The qualification of the organisation applying for the design approval certificate is reviewed in the context of the design approval procedure. The quality assurance measures for manufacture consist of three main steps. Pre-assessment of manufacturing documents such as quality plans, specifications etc., Manufacturing inspections according the pre-assessed documents and inspection before commissioning including documentation review. Periodic inspections during operation as well as relevant specifications for use and maintenance ensure that the properties specified in the approval certificate are preserved over the package life time. Special provisions for the return on experience regarding operational feedback for design, manufacture, use, maintenance and inspection are given.
Special focus shall be given here to the rearranged and meanwhile established system of manufacturing inspections. This includes more transparent roles for a) the producers authorised inspection

representative, b) the independent inspection expert (S), acting on behalf of the manufacturer with acceptance of BAM, and c) BAM or its authorised expert (BAM/T). Additional attention shall be drawn to the management of deviations during manufacturing and provisions for maintenance and periodic inspections.

Introduction

General

IAEA SSR-6 [1] §306 requires the establishment and implementation of a management system to ensure compliance with the relevant provisions of the IAEA-SSR-6 regulations [1]. This system is required for all activities within the scope of the regulations to ensure the objectives ("… to ensure safety and to protect people, property, and the environment from harmful effects of ionizing radiation during the transport of radioactive material" [1]). The objectives are achieved by establishing the requirements

- Containment of the radioactive contents,
- Control of external dose rate
- Prevention of criticality
- Prevention of damage caused by heat.

This includes, in accordance with IAEA SSR-6 [1] §106, design, manufacture, maintenance and repair of the packaging.

Depending on the level of radioactivity we differentiate between package designs requiring competent authority approval and package designs not requiring competent authority approval. The requirements for packages not requiring competent authority approval (Excepted packages, Industrial packages Type 1 (IP-1), 2 (IP-2) and 3 (IP-3) as well as Type A packages) are explained in BAM-GGR 016 [2], which shall not be discussed here.

In 2010 BAM published the BAM-GGR 011 guideline [3], which describes necessary quality assurance measures for design, manufacture, testing, documentation, use, maintenance and inspection of packagings for package designs requiring competent authority approval for the transport of radioactive material (Type B, Type C). In 2018 we decided to revise the guideline due to new developments. Hereafter we would like to present the main points of the guideline and subsequently explain the revision.

System of quality assurance measures

Requirements for quality assurance measures resulting from the above-mentioned statutory provisions are split into system-related and design-related measures.

System-related measures shall focus the organisational structure of the company or entity. They shall be organised as a quality management system or a quality management plan. Related explanations to this topic are given in the TS-G-1.4 [4]. BAM reviews system-related measures according to the

national guideline R 003 [5] and BAM-GGR 011 guideline [3] within the design approval procedure in three year cycles or after a justified occasion with suitable measures, e.g. a BAM-GGR 011 audit. Often the basis, but not prerequisite for this audit is a valid ISO 9001 [6] approval of the management system.

Design-related measures shall focus the actual design and all provisions in order to ensure compliance with requirements for design, manufacturing, testing, documentation, use, maintenance and inspection of the actual packaging. The design-related (for a safe operation required) parameters and characteristics shall be specified in the design documents (e.g. in drawings, parts lists, material specifications, working and testing instructions).

The required measures according to BAM-GGR 011 [3] may be divided into the eight topics illustrated in Fig. 1.

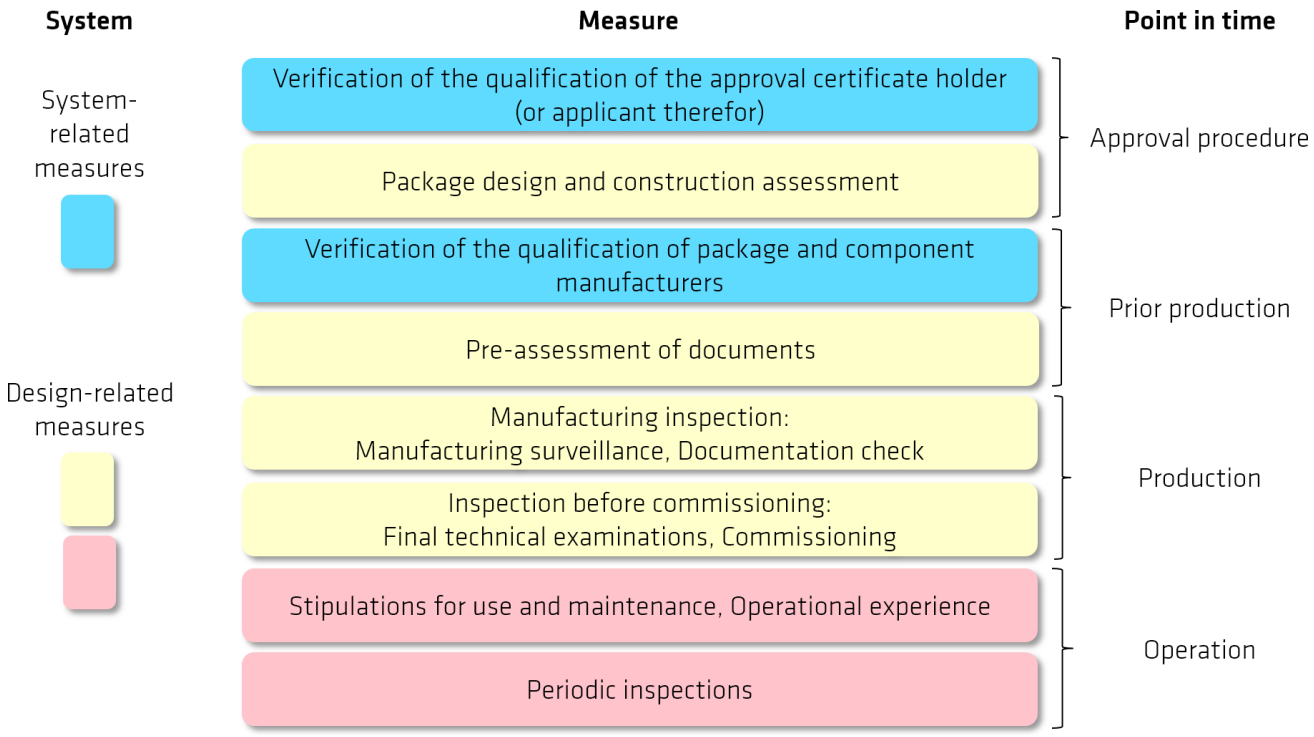

Fig. 1. System- and Design related measures according to BAM-GGR 011 [3]

Design and construction

Package requirements and classification levels

Design and construction shall be based on all parameters and characteristics (e.g. allowable quantity, physical, chemical and radiological properties of the content, operational and test requirements to the packaging, safety-relevant properties and functional parameters of the packaging, its components and materials), which must be taken into account to comply with the four requirements mentioned in the introduction.

All components and safety-relevant component parameters shall be classified according to three grades. If necessary this classification can be restricted on sections, features or manufacturing steps of a component. The following classification is to be applied:

Grade 1 All components and component parameters of this grade ensure directly the safety objectives *containment of the radioactive contents*, *control of external dose rate*, *prevention of criticality* and *prevention of damage caused by heat*.
Grade 1 also includes load attachment points or its components (trunnions or similar) of transport packages, which are liable to the scope of KTA 3905 [7].

Grade 2 All components and component parameters of this grade ensure indirectly the requirements mentioned in grade 1 for the attainment of the safety objectives.

Grade 3 All components which do not belong to grade 1 or 2.

Package design and construction assessment

The package design and construction assessment is performed according to the national guideline R 003 [5]. The required quality is documented by drawings, parts lists and material specifications. It is approved by BAM and declared binding thereafter in the approval certificate issued by the Federal Office for the Safety of Nuclear Waste Management (BfE).

Verification of qualifications

The system-related quality assurance measures according to BAM-GGR 011 consist of checking the licensee's or applicant's qualification and checking the manufacturer's qualification.

Qualification of license holder or applicant

The applicant shall have an established and implemented quality management system in order to ensure the requirements for design, construction, manufacturing, operation and maintenance of packages for the transport of radioactive materials. The quality management system is reviewed by BAM as part of the design approval procedure. Subsequently, the quality management system is reviewed at least in three year cycles or after justified occasion. The check is typically performed in form of quality audits.

Qualification of manufacturers

The manufacturer of the packaging and the manufacturers of grade 1 and grade 2 components shall have an appropriate quality management system to guaranty the required product quality. In particular, sufficient human resources and an adequate infrastructure must be available. The qualification is checked by BAM respectively BAM/T prior to manufacturing and is reassessed in three year cycles. In recertification quality audits and findings from production monitoring are considered, if necessary.

Manufacturing

The design-related documents for manufacturing of packagings and its components of grade 1 and 2 and possible repair measures are to be established as fabrication and test sequence plans (example available as appendix of the BAM-GGR 011 [3]).

The quality control in manufacturing is achieved by accompanying checks during pre-assessment, manufacturing inspection and the inspection before commissioning.

Pre-assessment

The pre-assessment envelopes verification and approval of documents which are needed to guarantee the requirements in accordance with the approval certificate while packaging manufacturing. The documents are fabrication and test sequence plans (FPP) including related working and testing instructions, welding plans, material testing plans and if applicable further documents for manufacturing and commissioning. The pre-assessment is carried out by BAM resp. its authorised expert (BAM/T) before manufacturing begins. The manufacturer has to check the timeliness in periods of maximum three years. BAM respectively its authorised expert (BAM/T) has to confirm the assessment.

Manufacturing inspection

The inspection is carried out by the responsible person in compliance with the pre-assessed documents accepted by BAM resp. BAM/T, especially the fabrication and test sequence plans.

- The inspection of grade 1 components or its monitoring is performed by the authorised inspection expert of the manufacturer respectively approval certificate holder and the independent inspection expert (S) as well as by BAM respectively its authorised expert (BAM/T). The inspection of grade 1 components ensuring directly the requirements *Prevention of criticality* and *Prevention of damage caused by heat* shall be carried out as for components of grade 2.
- The inspection of grade 2 components or its monitoring is performed by the authorised inspection expert of the manufacturer respectively the approval certificate holder. Monitoring of the assembling of impact limiting devices is performed according to a grade 1 part.
- The inspection of grade 3 components or its monitoring is performed according to the parts list.

The evidence shall be documented according to DIN EN 10204 [8]

- for grade 1 components by inspection certificate 3.2,
- for grade 2 components by inspection certificate 3.1,
- for grade 3 components as specified in the parts list.

An alternative procedure shall be agreed with BAM resp. its authorised expert (BAM/T), if such kind of documentation is not possible or applicable.

Deviations

In case of deviations in manufacturing, the approval certificate holder shall assess these deviations. The procedure is as follows:

- Deviations on grade 1 and grade 2 components must be reported to BAM. The acceptance of deviations requires BAM approval.
- Measures on grade 1 and grade 2 components caused by deviations require the acceptance by BAM before conduction. If applicable, documents shall be prepared and pre-assessed.
- Deviations on grade 3 components require the acceptance of the approval certificate holder.

Inspection before commissioning

The inspection before commissioning or its monitoring is performed by the responsible person according to the specified stipulations within the pre-assessed documents.

The pre-assessed documents shall ensure that every packaging has to be tested after manufacturing and assembling of all components and before commissioning to guarantee compliance with the design specification defined in the design approval certificate. Checking completeness and accurateness of manufacturing documents is part of the Inspection before commissioning procedure. The packaging shall be marked permanently with declaration of the period up to the next Periodic inspection by BAM respectively its authorised expert (BAM/T) after the successful Inspection before commissioning. Based on the design approval, the result of the inspection before commissioning shall be confirmed by BAM respectively its authorised expert (BAM/T) by a certificate. BAM keeps a directory of these certificates.

The procedure for components which are not attributed to a packaging during inspection before commissioning, such as impact limiters, shall be comparable and agreed with BAM.

Operation

The monitoring of packaging operation is determined by adequate provisions in the documents for use, maintenance and Periodic inspection of the packaging.

Use and maintenance

By creating and applying use and maintenance documents of a packaging it shall be ensured that the packaging is only used in the supposed manner. Therefore, the use and maintenance documents must, directly or by referring appropriate documents (e.g. approval certificate, inspection instructions), specify

- permitted contents and quantities,
- loading and unloading,
- secure fixation of the package,

- qualification of personnel and involved parties,
- all measures which must be taken to keep the packaging in a condition according to the regulations during situations like e.g. loading, trans-shipping, unloading, transportation or stops due to the transport,
- limit values to be kept,
- work and test instructions to be kept,
- maintenance activities and replacement of components,
- procedure for the case of deviations as well as the kind of documentation of deviations,

to keep the packaging in a condition according to the approval certificate, especially to protect personnel and third parties. The assessment of use and maintenance documents is performed by BAM within the design approval according to the relevant German guideline R 003 [5].

Periodic inspection

Packagings shall be inspected periodically to verify that the properties specified in the approval certificate are still met and that they are expected to be met until the date of next Periodic inspection. The period of time till the next inspection has to be determined taking into account the time dependency of safety-relevant material and component properties as well as type and frequency of use of the packaging.

In Germany, a period of three years and a maximum number of transports of 15 for a small and six years und 60 transports for a major periodic inspection is generally implemented.

Replacement components or repairs during periodic inspections are to be manufactured respectively executed according to the requirements of the BAM-GGR 011 guideline. A test plan for periodic inspections taking into account the above-mentioned requirements is to be established by the applicant respectively the approval certificate holder and to be assessed by BAM within the design approval procedure according to the national guideline R 003 [5].

The packaging has, after the successful inspection, by BAM or its authorised expert (BAM/T) to be marked permanently with the month and year of the next periodic inspection.

Operational experience

The license holder / applicant therefor shall define procedures regarding information feedback about the operational experience of the delivered packaging in the management system. The methods shall ensure an adequate consideration of this information for the further use of the design as well as for the development of other package designs.

Highlights of the guideline update

The transparent and clear assignment of roles within in the manufacturing system was, apart from the transfer of the current state of the art to the guideline, one of the main aims of the update. The relevant stakeholders and their relationships are shown in Fig. 2.

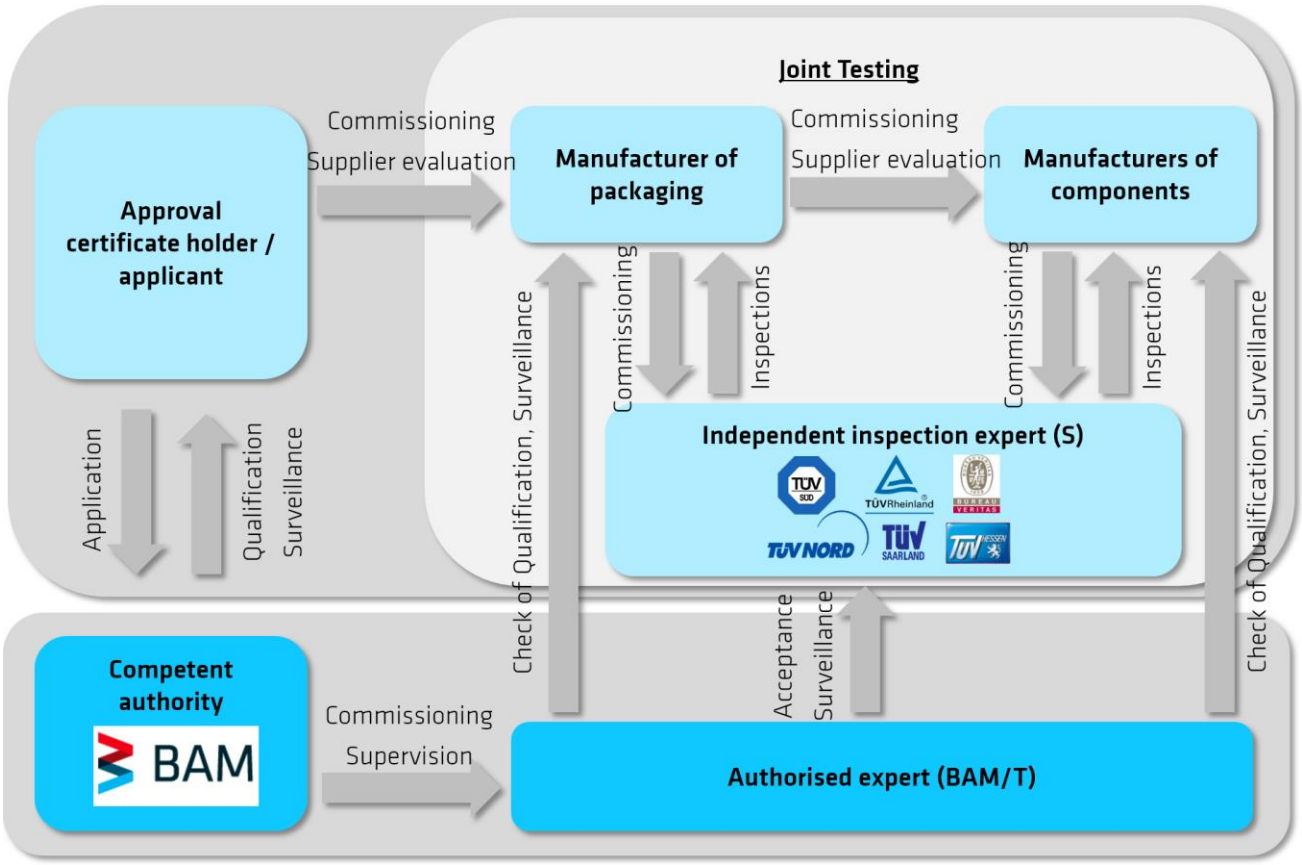

Fig. 2 Relevant stakeholders and their relationships within the BAM-GGR 011 [3] manufacturing system

In order to clarify the responsibilities, new names and new definitions for the independent inspection expert (S, formerly T2) and the authorised expert (BAM/T, formerly T1) were given:

Independent inspection expert (S)

> Independent inspection expert who acts on behalf of the manufacturer with acceptance of the competent authority and who is an authorised inspection representative in terms of DIN EN 10204 [8]

Authorised expert (BAM/T)

> Authorised expert of competent authority BAM. The working scope may include the function of an authorised inspection expert.

As visible in Fig. 2 there are two domains of responsibility. The competent authority commissions an authorised expert (BAM/T) who surveillances the whole manufacturing system independently from the license holder from a competent authority point of view. Manufacturers are qualified by BAM/T prior the start of manufacturing. Spot checks during the manufacturing ensure compliance.

Most likely the approval certificate holder is also the manufacturer of the packaging. Otherwise, the approval certificate holder commissions the manufacturer of the packaging. The latter commissions the manufacturers of components. The manufacturer commissions an independent inspection

expert (S) and requires the witnessing and inspection of relevant manufacturing or test steps, performed by the authorised inspection expert of the manufacturer, by the independent inspection expert (S) in accordance with the pre-assessed quality and test sequence plans. The work of both the authorised inspection expert of the manufacturer as well as the independent inspection expert (S) lies with the license holder. This clarification shall lead to more transparent lines of responsibility and strengthens the responsibility of the manufacturer of the packaging.

Conclusions

The guideline BAM-GGR 011 describes necessary quality assurance measures for design, manufacture, testing, documentation, use, maintenance and inspection of packagings for package designs requiring competent authority approval for the transport of radioactive material. Here, the main points of the guideline design and construction, manufacturing and operation were briefly described. One main point of the new revision was described: the clarification of responsibilities. The approval certificate holder / applicant therefor commissions manufacturers. They commission independent inspection experts (S), who witnesses and inspects - according to the pre-assessed documents. The competent authority with help of its authorised expert (BAM/T) surveillances the whole manufacturing system with a system consisting of qualifications and spot checks. This clarification shall lead to more transparent lines of responsibility and strengthens the responsibility of the producer of the packaging.

References

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