BAM

Bundesanstalt für
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Quality Assurance Measures of Packagings
for Competent Authority Approved Package Designs
for the Transport of Radioactive Material

Revision 1

Contact:

Division 3.3 “Safety of Transport Containers“

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1 Scope

The guideline describes necessary quality assurance measures for design, manufacturing, testing, documentation, use, maintenance and inspection of packagings for package designs requiring competent authority approval for the transport of radioactive material (hereafter package designs) to ensure that the requirements according to the following regulations as well as the specifications according to the design approval certificate are met.

Requirements of other legal provisions, e.g. requirements for transport casks or their components in nuclear power plants or requirements for casks for long-term interim storage and final disposal of radioactive materials as well as product liability provisions are not affected.

The guideline explains

- Ordinance on the Domestic and International Transport of Dangerous Goods by Road, Rail and Inland Waterways (Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße, mit Eisenbahnen und auf Binnengewässern GGVSEB),
- Ordinance on the Transport of Dangerous Goods by Sea (Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen GGVSee) und
- Luftverkehrs-Zulassungs-Ordnung (LuftVZO),

as far as, according to the above-mentioned legal provisions for the transport of radioactive materials in current version, on basis of the International Atomic Energy Agency (IAEA) recommendations for the safe transport of radioactive materials “Regulations for the Safe Transport of Radioactive Material – Specific Safety Requirements No. SSR-6”, the package design has to be approved by the competent authority,

for all designs of

- Type C, B(U) B(M) packages for radioactive materials,
- Packages for fissile material (CF, B(U)F, B(M)F, AF and IF),
- Packages for non-fissile or from the requirements on fissile materials excepted uranium hexafluoride (H(U) and H(M)).

2 Definitions for the purpose of this guideline

(1) Deviation

Deviation is the non-conformance of a detected condition to a (specified) nominal condition.

(2) Authorised inspection representative

Person with proven expertise and independence, who is commissioned by the applicant, approval certificate holder, manufacturer or the competent authority.

(3) Applicant

Natural person or legal entity applying for approval of a package design to the competent authority.

(4) Operation

Use, maintenance and periodic inspection of a packaging starting with inspection before commissioning.

(5) Manufacturer

Natural person or legal entity manufacturing packagings or components thereof.

(6) Manufacturing

Conversion of raw material and/or semi-finished products and the assembly of components to a packaging.

(7) Management system

See commentaries of SSR-6 /1/ and SSG-26 /2/ para. 228 for definitions linked with these terms.[1]

(8) Quality, Quality Management Handbook, Quality Management Plan, Quality Management System, Quality Assurance

See DIN EN ISO 9000 /3/ for definitions linked with these terms.

(9) 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 /4/.

(10) Authorised expert (BAM/T)

Expert of an independent inspection organisation, authorised by the competent authority BAM. The field of activity may include the function of an authorised inspection representative.

(11) Approval certificate holder

Natural person or legal entity holding a design approval certificate according to guideline R 003 /5/.

3 Competence

The applicant/approval certificate holder is responsible for the determination of quality assurance measures during design, manufacturing, testing, documentation, use, maintenance and inspection of package designs.

The approval certificate holder is responsible to hand over with each packaging the documents containing the quality assurance measures for the operation of the packaging to the competent person/company, who/which use the packaging. The person/company competent for operation of the packaging is responsible for the realisation of quality assurance measures during use.

[1] According to IAEA SSG-26 para 228.2, the term management system was introduced into SSR-6 by replacing the term quality assurance. A management system in the sense of the IAEA regulations includes a quality management system.

The competent authority for approval and surveillance of quality assurance measures for design, construction, manufacturing, operation, maintenance and periodic inspection of packagings for designs requiring competent authority approval is the

Bundesanstalt für Materialforschung und -prüfung (BAM)
Unter den Eichen 87,
12205 Berlin, Germany).

4 Quality Assurance Measures

4.1 Background

4.1.1 General

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

4.1.2 System related measures

A quality management system shall be established (in written form) and implemented in order to ensure compliance with requirements for design, manufacturing, testing, documentation, use, maintenance and inspection of packagings for the transport of radioactive materials. Requirements for quality management systems are described e.g. in DIN EN ISO 9001 /6/.

Documents describing system-related measures shall be submitted within the approval procedure of package design for transport of radioactive material.

System-related procedures 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 /7/.

BAM reviews the system-related measures of the applicant respectively approval certificate holder according to the guideline R 003 /2/ within the design approval procedure in three year cycles or after a justified occasion with suitable measures, e.g. an audit. BAM or an external expert issues a certificate of reviewing.

4.1.3 Design related measures

Quality assurance measures shall be established to ensure compliance with requirements for design, manufacturing, testing, documentation, use, maintenance and inspection of packagings. The appropriate dangerous goods regulations define the requirements for the packagings of the package design.

The applicant shall ensure that the design-related, for a safe operation required parameter and characteristics are specified in the design documents (e.g. in drawings, parts lists, material specifications, working and testing instructions).

4.2 Design and construction

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 package requirements

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

ensuring the safety objectives[2] regulated for transport.

All components and safety-relevant component parameters shall be classified according to three levels. If necessary this classification can be restricted on sections, properties or manufacturing phases of a component.

The following classification is to be applied:

Grade 1 All components and component parameters of this grade ensure immediately 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 of transport packages (trunnions or similar) or its components, which are subject to the scope of KTA3905.

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.

A further classification of requirements for components of the same grade can be done according to the package design.

The specifications for particular components of a package design have to be adapted to each other for manufacturing and operation according to their safety function.

Design and the construction shall consider all relevant requirements of regulations, standards and instructions. The verifiability of safety-relevant properties shall be ensured.

The package design and construction assessment are performed according to the 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).

[2] The safety objectives are, according to e.g. ADR, to ensure safety and to protect people, property, and the environment from harmful effects of ionizing radiation during the transport of radioactive material.

4.3 Manufacturing

4.3.1 General

The manufacturer of packagings or grade 1 and 2 components is obliged to implement an appropriate quality management system. Sufficient human resources and adequate infrastructure for guaranteeing product quality must be available. Evidence about qualification of manufacturers shall be presented to BAM or its authorised expert before the manufacturing begins. It will be reassessed in three-year cycles.

The quality control of manufacturing is done by accompanying checks by pre-assessment, production control and the inspection before commissioning.

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 see appendix). Production on automatic lines may be excluded in agreement with BAM.

4.3.2 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 including related working and testing instructions, welding plans, material testing plans and if applicable further documents for manufacturing, commissioning and repair. The pre-assessment is carried out by BAM respectively its authorised expert (BAM/T) before manufacturing begins. The manufacturer has to check the timeliness in periods of maximum three years. BAM respectively its external expert (BAM/T) has confirm the assessment.

4.3.3 Manufacturing inspection

The inspection is carried out by the responsible person in compliance with the stipulations of pre-assessed documents accepted by BAM, especially the fabrication and test sequence plans. The responsibility is designated according to the classification of the inspected component or its properties according to section 4.2 of this guideline.

- The inspection of grade 1 components or its surveillance is performed by the authorised inspection representative of the manufacturer respectively approval certificate holder and the independent inspection expert (S) as well as by BAM respectively its authorised expert. The inspection participation shall be specified in pre-assessed documents.

  The inspection of grade 1 components ensuring immediately the requirements control of external dose rate 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 surveillance is performed by the authorised inspection expert of the manufacturer respectively the approval certificate holder

  Surveillance of the assembling of impact limiting devices is performed according to a grade 1 component.

- The inspection of grade 3 components or its surveillance is performed according to the parts list.

The evidence shall be documented according to DIN EN 10204 /4/

- 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 respectively its authorised expert (BAM/T), if such kind of documentation is not possible or applicable. If applicable shall documents be prepared and pre-assessed according to section 4.3.2.

If particular evidence for manufacturing or testing is needed, it shall be accounted to BAM, e. g. as material assessment or procedure verification before the manufacturing begins.

4.3.4 Deviations

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

- deviations in 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 shall documents shall be prepared and pre-assessed according to section 4.3.2.
- deviations on grade 3 components require the acceptance of the approval certificate holder.

Whenever deviations may influence the requirements control of external dose rate or prevention of criticality, the approval certificate holder shall obtain a BfE statement before acceptance or the beginning of measures.

4.3.5 Inspection before commissioning

The inspection before commissioning or its surveillance is performed by the responsible person according to the by BAM respectively BAM/T accepted stipulations within the pre-assessment documents. The responsibilities are defined according to the classification grade of the component of the design according to section 4.2 and 4.3.3 of this guideline.

The pre-assessment documents according to section 4.3.2 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 procedure before commissioning. 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 by a certificate. The certificate shall be sent to BfE and BAM unless BAM has exclusively performed the inspection before commissioning. This certificate confirms the compliance of the particular packaging with the specified design. BAM keeps account of these certificates. The procedure for components, which are not assigned to a packaging during inspection before commissioning such as impact limiters, shall be comparable and agreed with BAM.

Deviations identified during inspection before commissioning shall be treated according to section 4.3.4.

4.4 Operation

4.4.1 General

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

4.4.2 Use and maintenance

By creating and applying use and maintenance documents of a packaging it is 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, transshipping, 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 assessment according to the guideline R 003 /5/.

4.4.3 Periodic inspection

Packagings have to 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 shall 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.

The period until next inspection may not be exceeded and ends in the defined month.

For empty packagings with overdue inspection, the inspection must be made before the next use at the latest.

Replacement components or repairs during periodic inspections are to be manufactured respectively executed according to this guideline.

A test plan for periodic inspections taking into account the above-mentioned requirements shall be established and assessed by BAM within the design assessment according to the guideline R 003 /5/.

The documentation of the packaging (material certificates, inspection results and results from manufacturing, approval, and former periodical inspections, if existent) must be available for the periodic inspection.

The result of every periodic inspection shall be confirmed by BAM or its authorised expert (BAM/T) by a certificate. This certificate shall be sent to BAM, unless BAM performed the periodic inspection itself. The compliance of the particular packaging with the specified design is confirmed with this certificate. BAM keeps account of these certificates.

The packaging shall be marked permanently with the specification of the period up to the next periodic inspection by BAM or its authorised expert (BAM/T) after the successful inspection.

Deviations identified during periodic inspection shall be treated according to section 4.3.4.

4.4.4 Operational experience

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

4.5 Dokumentation

The Documentation shall be performed according to the definitions of quality assurance measures. In particular, design specific documents, specifications, qualification certificates, supporting documents, inspection results and other results of design, manufacturing, testing, documentation, use, maintenance and inspection of packagings, which show the compliance with the transport regulations for the packaging, have to be documented and kept for each packaging during the period of operation. The documentation must be made available to the competent authority on request.

Documentation is to be summarised in a logbook for each packaging. It must include at least:

- approval certificate
- certificate of inspection before commissioning
- instructions for use and maintenance
- inspection plan for periodic inspections
- certificates of periodic inspections
- documents about the use of the packaging, recordings about replaced components, repairs and particular incidents (deviations/changes)
- work and test instructions used for loading.

4.6 Miscellaneous

4.6.1 Other specifications regarding quality assurance

If measures of quality assurance and quality control within the scope of other requirements are legally bindingly arranged, BAM may accept these measures alternatively.

4.6.2 Package designs approved by other countries

In case of package designs which are approved by other countries, BAM may ask for a confirmation of comparable measures of quality assurance and quality control, as far as the competence of BAM is concerned. Measures of compensation have to be stipulated, if necessary. Provisions of the R 003 /5/ shall be respected.

5 Fees

The fees for assessment and inspection have to paid by the applicant. Fees arising by BfE and BAM depending on expense according to the institutions' procedures for charging fees, based on the relevant national ordinance "Kostenverordnung für Maßnahmen bei der Beförderung gefährlicher Güter (GGKostV)". The hourly rate for the calculation of fees for the BfE is fixed in the valid version of the instruction "Dienstanweisung über die Erhebung von Gebühren und Auslagen im Bundesamt für kerntechnische Entsorgungssicherheit (BfE)".

6 References

/1/ SSR-6: Regulations for the Safe Transport of Radioactive Material, International Atomic Energy Agency (IAEA), Vienna, 2012.

/2/ SSG-26: Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, International Atomic Energy Agency (IAEA), Vienna, 2012.

/3/ DIN EN ISO 9000: Qualitätsmanagementsysteme - Grundlagen und Begriffe (ISO 9000:2015), (Quality management systems - Fundamentals and vocabulary), Edition November 2015.

/4/ DIN EN 10204: Metallische Erzeugnisse - Arten von Prüfbescheinigungen (Metallic products – Types of inspection documents), Edition January 2005.

/5/ R 003 - Guideline for the design approval procedure of packages for the transport of radioactive material, of special form radioactive material, low dispersible radioactive material and excepted fissile material. VkBl. 2016 S. 430, 9. Juni 2016, translation by BfE, March 2017. https://www.bfe.bund.de/SharedDocs/Downloads/BfE/EN/genehmigungsunterlagen/behaelterzulassung/r003-en.pdf

/6/ DIN EN ISO 9001: Quality management systems – Requirements), Edition November 2015.

/7/ TS-G-1.4: The Management System for the Safe Transport of Radioactive Material, International Atomic Energy Agency (IAEA), Vienna, 2008.

Manufacturer: *Logo, Name*	**Fabrication and Test Sequence Plan (FPP)** ***Title***	FPP-No., Rev.:	Page: ... of ...
		Identification-No.:	Quantity:

Package design: Part:	Drawing-No.: Material:	Order-No. H: Order-No. K:

Fabric. Step No.	Test Step No.	Description of Fabrication resp. Test Step	Fabrication resp. Test Specification	Check by				Proof	Confirmation				Comments	Proof No. (Certificate, Protocol, Sketch etc.)
				H	K	S	BAM/T		H	K	S	BAM/T		

Creator	Confirmation of Pre-Assessment		
H: Date, Name	H: Date, Signature, Stamp	K: Date, Signature, Stamp	BAM/T: Date, Signature, Stamp
	Confirmation of Documentation Review		
	H: Date, Signature, Stamp	K: Date, Signature, Stamp	BAM/T: Date, Signature, Stamp

Explanations

X = Mandatory participation
(X) = Invitation required, participation based on surveillance programme

H = Authorised inspection representative of the manufacturer
K = Customer

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
BAM/T = Authorised expert of competent authority BAM