BAM
Bundesanstalt für Materialforschung und -prüfung

Remark

The german version is the only legally binding text.

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BAM-GGR 016

Measures for quality and ageing management for non-competent authority approved package designs for the transport of radioactive material

Revision 1

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Contents

1 Scope

The guideline describes necessary requirements for management systems for design, manufacturing, testing, documentation, use, maintenance and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval to ensure compliance with following regulations:

- Agreement concerning the International Carriage of Dangerous Goods by Road. Übereinkommen vom 30. September 1957 über die internationale Beförderung gefährlicher Güter auf der Straße (ADR) (BGBl. 1969 II S. 1489), Anlagen A und B in der Fassung der Bekanntmachung vom 16. November 2021 (BGBl. 2021 II S. 1184), die zuletzt durch die 29. ADR- Änderungsverordnung vom 22. November 2022 (BGBl. 2022 II S. 601) geändert worden ist [1],
- Regulations concerning the International Carriage of Dangerous Goods by Rail. Übereinkommen über den internationalen Eisenbahnverkehr (COTIF), Anhang C – Ordnung für die internationale Eisenbahnbeförderung gefährlicher Güter (RID) vom 9. Mai 1980 (BGBl. 1985 II S. 296) in der Fassung der Bekanntmachung vom 22. April 2022 (BGBl. 2022 II S. 279), die zuletzt durch die 23. RID-Änderungsverordnung vom 3. November 2022 (BGBl. 2022 II S. 555) geändert worden ist [2],
- European Agreement concerning the international Carriage of Dangerous Goods by Inland Waterways. Europäisches Übereinkommen vom 26. Mai 2000 über die internationale Beförderung von gefährlichen Gütern auf Binnenwasserstraßen (ADN) (BGBl. 2007 II S. 1906, 1908), Anlage in der Fassung der Bekanntmachung vom 10. November 2021 (BGBl. 2021 II S. 1150), die zuletzt durch die 9. ADN-Änderungsverordnung vom 14. Dezember 2022 (BGBl. 2022 II S. 690) geändert worden ist [3] und
- International Maritime Dangerous Goods Code (IMDG Code), Amendment 41-22, in der amtlichen deutschen Übersetzung bekannt gegeben im Dezember 2022 (VkBl. 2022 S. 829) [4].

The responsibilities of BAM in connection with this guideline are settled in the following ordinances:

- Ordinance on the Domestic and International Transport of Dangerous Goods by Road, Rail and Inland Waterways – GGVSEB [5],
- Ordinance on the Transport of Dangerous Goods by Sea - GGVSee [6]) and
- Luftverkehrs-Zulassungs-Ordnung [7],

Consecutively only the ADR [1] as well as the GGVSEB [5] will be referred to. The references to RID [2], ADN [3] and IMDG [4] as well as to GGVSee [6] and Luftverkehrs-Zulassungs-Ordnung [7] apply in its current version correspondingly.

This guideline explains the regulations in regard to required measures for quality and ageing management for all package designs of:

- Exempted packages,
- Industrial Packages of Type IP-1, IP-2 and IP-3 and
- Packages of Type A.

Requirements of other regulations are not affected.

2 Definitions for the purpose of this guideline

The definitions ADR [1] apply if not stated otherwise.

Authorised inspection representative	Person with proven expertise and independence who is commissioned by the manufacturer.
Certificate of acceptance Declaration of?	Declaration by an Authorised inspection representative specifying compliance of a manufactured packaging with the specified package design.
Consignor	Enterprise which consigns dangerous goods either on its own behalf or for a third party. If the transport operation is carried out under a contract for carriage, consignor means the consignor according to the contract for carriage.
Deviation	Non-conformance of a condition to a nominal condition.
Modification	Change of the nominal specification.
Ageing	Alteration of components/component groups of a package/package design due to ageing mechanisms during package operation.
Ageing effects	Consequences of ageing mechanisms concerning a package design which lead to alteration of a package considering the assessable/foreseeable operating time due to e. g. material removal due to corrosion, alteration of strength resulting from thermal loads, plastic deformation due to creep.
Ageing management	Entirety of organizational and technical measures that ensure the packaging/package conformity to the specification starting from commissioning until decommissioning of a package design.
Aging management plan (AMP)	Ageing induced alterations at packagings/packages of a package design shall be anticipated in the AMP during package operation. If applicable, measures for their control and monitoring shall be defined. The handling of the evolution of regulatory framework and safety case methods shall be stipulated.
Ageing mechanisms	Known physical, chemical, or biological processes that may induce alterations in material and component structure and properties. This encompasses e. g. varied kinds of corrosion, radiolysis, creep, relaxation, wear and fatigue.
Ageing surveillance program (ASP)[1]	The ASP comprises all measures for monitoring and control of predicted alterations that may jeopardise the conformity to the specification of a package design.
Applicant	Natural person or legal entity applying for an acceptance of a management system for design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for the transport of radioactive material for package designs not subject to competent authority approval. This is the originator of

[1] In the German version AÜP

	the Certificate of compliance and Certificate of acceptance, if applicable.
Contractor	Company / company part which is contracted with the provision of activities and whose management system is not part of the management system acceptance by the competent authority.
Operation	Use, maintenance, and periodic inspection of a packaging starting latest with inspection before commissioning.
Operation time	Period of operation of a package/packaging starting with inspection before commissioning until decommissioning in the relevant field of law.
Certificate of compliance	Declaration by the applicant that the package design meets the requirements of the transport regulations based on a package design safety assessment (see appendix 2).
Manufacturer	Natural person or legal body who manufactures or lets others manufacture packagings.
Manufacturing	Conversion of raw material and/or semi-finished products and the assembly of components to a packaging.
Management system	See commentaries of SSR-6 [8], SSG-26 [9] para. 228 and ADR [1] section 1.2.[2]
Test book	Packaging specific documentation of measures for quality assurance during package operation. The documentation encompasses all during operation generated documents regarding quality assurance such as e. g. documentation of maintenance and inspection and results of the ageing surveillance programme.
Quality, Quality management, Quality management plan, Quality management system, Quality assurance, Quality manager	Please refer to the explanations in e. g. DIN EN ISO 9000 [10] regarding the relevant definitions for these terms.
Monitoring check	A check conducted by the External inspection agency's auditor regarding the manufacturer's quality records, as well as objective spot checks of packagings from ongoing production to ensure compliance with the QM plan approved by BAM and the manufacturing documents stated therein.
External inspection agency	External inspection agency resp. its auditor approved by BAM to conduct monitoring checks.
External expert	Expert from an independent testing organisation contracted and approved by BAM.

[2] 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. According to IAEA SSG-26 [9] §228.2 the term management system was introduced into SSR-6 [8] by replacing the term quality assurance. A management system in the sense of the IAEA regulations includes a quality management system.

3 General provisions and competences

3.1 General

For all activities regarding design, manufacturing, testing, documentation, as well as for the **determination** of measures for use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval a management system acceptance by BAM is to be obtained. This applies to the originator of the Certificate of compliance and/or Certificate of acceptance. Management systems for **execution** of measures for use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval are exempted obligation of acceptance. (Compare 1.7.3 ADR [1]).

Management systems for packagings for exempted packages and Industrial Packages Type IP-1 are exempted from acceptance and surveillance by BAM.

BAM may alternatively recognise other measures if these measures regarding quality assurance and surveillance are made mandatory by other requirements.

All documents may generally be provided to BAM by simple electronic means (e. g. PDF by E-Mail).

3.2 Applicant

The applicant is responsible for the determination of quality measures regarding design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval. They are to be presented during the acceptance process.

The application for an acceptance of the management system for packages not requiring competent authority approval is to be filed at BAM. Annex 1 shows minimal requirements for the application.

The applicant holds overall responsibility for the manufacturing. Shall the manufacturing be performed under the responsibility of a third party, then the third party shall be appointed during management acceptance. The management system of the third party shall be reviewed within the review of the applicant's management system. The fort he manufacturing scope accepted party issues the Declaration of acceptance (compare 5.4).

The applicant shall ensure that for each packaging with commissioning instructions for use including measures for quality assurance and ageing management are forwarded to the person or company responsible for package operation.

3.3 Competent authority

In Germany the competent authority for design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval pursuant this guideline according to GGVSEB [5] is the

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BAM grants an acceptance of a management system for the package-specific measures for design, manufacturing, testing, documentation as well as for the determination of measures for use, maintenance and inspection of a package design or a group of designs with a validity period of generally three years. An extension of the management system acceptance may be granted, assuming

timely application (three month before end of validity) and review by BAM. An earlier review may be required in case of substantiated reason.

BAM is entitled to inspection of management systems of all entities taking part in design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval.

3.4 Consignor

The consignor is according to ADR [1] 1.4.2.1.1 required to hand over for carriage only consignments which conform to the requirements. This encompasses ensuring that the measures for quality assurance and ageing management during package operation have been performed und documented (e. g. periodic test inspection certificates or corresponding packing marking). The consignor may according to ADR [1] 1.4.2.1.2 rely on the information and data made available to him by other participants.

4 Management system provisions

4.1 General

A management system for control and direction of the applicant's organisation is to be stipulated in written form and implemented for ensuring compliance according to ADR [1] 1.7.3 regarding design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval. The requirements are thereby divided into system related and design related measures.

4.2 System related measures

Documents describing the system-related measures of the applicant are to be presented within in application process. Requirements for quality management systems are described e. g. in DIN EN ISO 9001 [11]. Related explanations to this topic are given in the TS-G-1.4 [12].

BAM reviews the system-related measures of the applicant within the management system acceptance procedure in three-year cycles or after a justified occasion with suitable measures, e. g. an audit.

Appropriate human resources and infrastructure should be provided and applied by the applicant for design, manufacturing, testing, documentation and if applicable for use, maintenance, and inspection. This is valid especially for e. g. the performance of drop tests and design calculations. Corresponding qualification verifications are held available.

4.3 Design related measures

Design related requirements for quality assurance regarding design, manufacturing, testing, documentation, use, maintenance, and inspection of packagings for package designs for the transport of radioactive material not requiring competent authority approval shall be stipulated in form of a Quality Management Plan (QMP). The QMP manages all package design related aspects of the quality assurance. These are in particular:

- Construction, design, assessment, permitted content, documentation table,
- Supply of materials and components,
- Manufacturing of packagings,

- Quality monitoring, measures for modifications and deviations,
- Inspection before commissioning and its documentation, issuing of certificates,
- Instructions for use, maintenance, and inspection,
- Ageing management,
- Procedures for modifications,
- Operational experience.

The quality management plan is to be submitted to BAM for review before its application. BAM issues an acceptance of the management system generally limited to three years after successful review of the quality management plan in connection with the inspection of the relevant aspects of the management system. The in the QMP defined measures for quality assurance are thereby engaged.

5 Quality management plan

5.1 Design

Design and construction shall be based on all parameters and characteristics (e. g. operational and test requirements to the packaging, safety-relevant properties and functional parameters of the packaging, its components and materials, physical, chemical and radiological properties of the content, allowable quantity), which must be taken into account to comply with the package requirements of ADR [1]

- Loss or dispersal of the radioactive contents and
- More than a 20% increase in the maximum radiation level at any external surface of the package

All components and safety-relevant component parameters shall be classified according to TS-G-1.4 [12] into three levels. If necessary, this classification can be restricted on sections, properties, or manufacturing phases of a component.

Grade 1	Components and component parameters ensuring immediately the safety objectives loss or dispersal of the radioactive contents and increase in the maximum radiation level
Grade 2	Components and component parameters ensuring indirectly the safety objectives loss or dispersal of the radioactive contents and increase in the maximum radiation level
Grade 3	All components which do not belong to grade 1 or 2.

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 e. g. by experimental and/or numerical as well as analytical analysis of prototypes, serial specimens and models. The BAM-assessment of a management system shall include the third party, when the design assessment or essential parts thereof shall be performed by that third party. Corresponding qualifikation proofs shall

be provided in the management system acceptance procedure. Accredited test laboratories are exempted from the requirement for BAM acceptance.

Regarding documentation please refer to section 5.4.

5.2 Manufacturing

General

The manufacturing of packagings and possible repair measures are to be established as fabrication and test sequence plans according to appendix 7 or in equivalent digital form. The sequence of working and test steps is determined in the quality plan under reference to:

- Specifications in form of part lists and technical drawings,
- Material specifications or similar,
- Work and test instructions, incl. admissible criteria,
- Test participation,
- Type and scope of proof and documentation

Forms or electronic equivalents may be used to enter test records, and may also contain source references to other documents, such as test reports. The applicant performs the pre-assessment and approves the fabrication and test sequence plans and associated documentation.

The manufacturer shall ensure compliance of all material / part properties with the design specification. Proofs may e. g. be acceptance certificates own measurements. These shall be documented e. g. during incoming inspections. The material properties of grade 1 components shall be proven by an acceptance certificate according to DIN EN 10204 [13]. If the afore mentioned proof cannot be provided, an equivalent test may be performed. The confirmation of quality control of manufacturing shall be performed by the Authorized inspection representative.

Procedure for deviations

If deviations are detected during production or acceptance, causes and effects of these deviations shall be identified, evaluated, and the results shall be documented. Tolerated deviations shall be enlisted in the certificate of acceptance.

The applicant shall also check whether deviations extend to packagings already produced and delivered. The applicant shall in this case establish suitable measures.

If the deviation is caused by a deficiency in the quality assurance measures or implementation thereof, the applicant shall timely present the consequences, incl. remedial action, to BAM. The QMP may need to be adjusted and submitted for re- acceptance. BAM may specify further measures and, if applicable, additional assessments.

5.3 Testing

Requirements for quality assurance measures regarding design and assessment are available in section 5.1.

All packagings shall be inspected by the Authorised inspection representative before commissioning to prove compliance with the package design specifications once all components have been manufactured and assembled. The inspection scopes for manufacturing of components and the packaging necessary test steps shall be determined the QMP. The required test steps shall be detailed in test plans (e. g. as part of the fabrication and test sequence plans as per section 5.2). Checking the documentation for completeness and accuracy shall also be part of the inspection before commissioning.

5.4 Documentation

General

The documentation shall comply with the provisions established in the QMP. It is recommended to document and retain the design-specific documents, specifications, proof of qualification, records, test and other results relating to design, construction, production, acceptance and operation for each packaging during packaging operational period in analogue or digital form.

Design

Compliance with the hazardous goods regulations in terms of this guideline (compare ADR [1] section 5.1.5.2.3) shall be confirmed by a **Certificate of compliance** by the applicant based on a package design safety assessment documented in the form of a safety report. Recommendations for the structure of a safety report are given in [14]. Minimum requirements for a Certificate of compliance under consideration of SSG-26 [9] § 801.3 are given in appendix 2.

Manufacturing

All packagings shall be permanently marked with an ID number. Additional labelling may also be required by the instructions for use, maintenance, and inspection. The date for the next periodic inspection shall be marked for packages requiring periodic inspections.

Testing

The Authorised inspection representative shall issue **Certification of acceptance** once the inspection before commissioning is successfully completed, declaring the packaging compliance with the package design. This certification shall clearly identify the QM plan (with reference to its BAM acceptance) under which the respective packaging was manufactured. Additional requirements may be found in appendix 3. The manufacturing and testing documentation shall be compiled and disclosed to the competent authority upon request.

Use

Documentation requirements for use of the packaging / package are to be set in the instructions for use and if applicable are to be integrated (compare section 5.6) in the packaging specific documentation (e. g. as test book). This applies to e. g. requirements for service life, count of cycles and to periods of tours for packagings for repeated use or transportation after storage.

Maintenance and Inspection

Requirements for documentation during maintenance and inspection are to be stipulated in the instructions for maintenance and inspection. Measures for maintenance and inspection already performed may if applicable be integrated in a packaging specific documentation (e. g. as test book). This applies to e. g. exchange of parts as well as performed periodic inspections (comp. section 5.6).

5.5 Use

The applicant shall establish instructions for use including requirements in context of proper closing of the package and preparation for shipment (compare ADR [1] 4.1.9.1.9). These instructions shall protect the operation personnel and guarantee packaging quality during the service life. The instructions for use shall link requirements for maintenance and inspection, if applicable. Requirements may be found in appendix 4.

5.6 Maintenance and inspection

Packagings not intended for single use are to be inspected periodically regarding compliance with safety relevant properties and maintained. Instructions for maintenance and inspection are therefor to be determined. These instructions may be combined with instructions for use.

These instructions shall at least contain the following requirements respectively provisions for:

- Qualification of staff and participating entities,
- Applicable work and test instructions,
- work and test equipment to be used,
- Specifications for maintenance and inspection, repair measures, replacement of parts
- Stipulations for packaging ageing management
- Periods and course of action in the event of deviations and changes
- Type and scope of documentation.

The test periods shall be established by the applicant, considering time dependence of safety-relevant material and component properties, as well as in accordance with the type and frequency of operation. Successful completion of the checks shall be documented.

Replacement of parts respectively repair measures during maintenance and inspection shall be manufactured respectively performed according to this guideline.

All packagings shall be permanently marked with the period to the next periodic inspection.

In case of deviations shall be proceeded according to section 5.2.

6 Surveillance

6.1 General

The compliance with measures for quality assurance during manufacturing is randomly monitored by BAM and an external inspection agency, accredited by BAM for class 7. BAM respectively external inspection agency shall be permitted access to the manufacturing sites as well as provided insight into all relevant documents und documentations cording to the QMP.

Monitoring by the external inspection agency

The applicant shall contractually arrange monitoring inspections with an accredited external inspection agency, insofar as these are not performed by BAM. The BAM shall be informed in case of major changes during the management system acceptance period.

Intervals for the execution of monitoring inspections are set and periodically reviewed by BAM considering the packaging complexity, the amount of manufacturing and test steps as well as the number of packagings to be manufactured in general during management system acceptance process. A minimum of one monitoring check per year shall be performed during ongoing manufacturing.

BAM participation

BAM may always take part in monitoring inspections. Bam shall therefor timely be informed of planned monitoring inspections by the external inspection agency.

Execution of inspections

All relevant documents according to the QMP regarding manufacturing, testing, and documentation as well as samples from ongoing manufacturing shall be provided to BAM respectively external inspection agency. BAM respectively external inspection agency shall also be given access to equipment and measuring devices, if required.

Documentation of external inspection

A report shall be filed concerning the performed inspections by the external inspection agency. Minimum requirements for information to be documented may be found in appendix 6.

The original issue of the report shall be signed by BAM respectively the external inspection agency and remains with the manufacturer. The Authorised inspection representative of the manufacturer documents his acknowledgement by signature on the report. The external inspection agency shall forward a copy of the report including signatures to BAM. The manufacturer shall retain monitoring reports for at least 10 years.

6.2 Process for accrediting external inspection agencies

External inspection agencies and their auditors shall be accredited by BAM if they meet the requirements as per appendix 5. Accreditation shall be applied for stating the legal form of the external inspection agency, independence, and quality management, as well as the competence of the acting persons. It shall be limited and granted for three years, in accordance with the proven qualifications for monitoring checks and/or assessments. It may be extended for a further three years if a renewed check shows compliance with the relevant requirements. Extensions must be requested from the BAM promptly (3 months) before accreditation expiry.

The accreditation may be cancelled by BAM at any time for justified reason or if the duties of disclosure to the BAM are not sufficiently met.

Once accredited, the external inspection agency is included into the BAM's public directory of accredited external inspection agencies, with its contact details.

BAM must be immediately informed of any changes to the requested or existing accreditation, particularly if these relate to the acting persons.

6.3 Equipment and devices

The equipment and devices shall be suitable for measurement and testing tasks, and they shall be properly maintained in accordance with documented procedural instructions and directives. The measuring devices shall be calibrated at set intervals insofar as is necessary to ensure quality-based results.

6.4 Procedure for identification of defects during monitoring inspections

Defects associated with the compatibility and implementation of quality assurance measures detected during monitoring inspections shall immediately be reported by the external inspection agency to BAM.

BAM may then:

- set additional monitoring measures for the manufacturer,
- conduct assessments and monitoring checks upon specific reason,
- prohibit further manufacturing until defects are remedied,
- in serious/repeated cases withdraw the QM plan acceptance.

7 Modifications

Once a package design should be modified, the applicant shall be responsible for creating a document describing and assessing the modification. The applicant shall particularly check and assess the extent of safety relevance and whether requirements of the relevant regulations are still fulfilled. If necessary, all or part of the package design assessment may need to be re-conducted. The design specification and Certificate of compliance are to be adapted.

The QMP shall be submitted to BAM for re-assessment and acceptance if this modification or a separate modification of the quality assurance measures requires an adjustment of the QMP.

Modifications of a design specification is not permitted if there is no valid management system acceptance. Remodelling of a packaging may only be performed in compliance with the package design specification (documented modifications by the applicant in written form by e. g. modification certificates).

8 Operational experience / organisation of experience feedback

The applicant shall establish procedures guaranteeing information feedback on noticeable problems during packaging operations as part of the quality assurance measures including findings resulting from ageing surveillance. This information shall be appropriately considered both in further operation and design of new packages.

All entities taking part in use, maintenance and inspection are compelled to participate in experience feedback.

The applicant and BAM, if applicable, shall be informed immediately upon identification of important safety relevant deficits. The packaging shall not be used until clarification respectively rectification. Packagings of the same design shall be inspected for this deficit, if applicable.

9 Ageing management

9.1 General

The applicant shall define ageing management measures for non-approved packages. In accordance with ADR [1] 1.7.3, 6.4.2.8, this includes the consideration of ageing mechanisms and ageing effects regarding the package design and the specification of measures to control ageing during the operation of packaging. These measures may also include specifications for a maximal service life of components/component groups (e. g. elastomer seals, coatings) or of complete packagings.

BAM reviews the specifications on the ageing management measures required for operation as part of the acceptance of the management system, regularly as part of the renewal of the management system acceptance or upon substantiated reason.

9.2 Package classification by means of use

The intended type of use for a packaging is decisive for the determination of measures concerning ageing management. This determination of measures is also dependent on the accessibility and replaceability of components/component groups. Subsequently, a classification resulting from package operation into three different groups is performed here. In this guideline, storage may be defined as a

period without transport for which it is assumed that ageing mechanisms may cause relevant changes to the package.

Packages intended for single use

Measures for ageing management may be omitted for packages that are foreseen for one-time use only without prior storage between loading and transport. Ageing mechanisms and their consequences are to be assessed during package design phase.

Packages intended for repeated use

Ageing mechanisms and their consequences during package operation shall be assessed for packages intended for repeated use. Corresponding measures shall be implemented within the ageing management (AMP) e. g. in the plans for periodic inspections.

Packages intended for transport after storage

Packages intended for transport after storage are subject to special constraints. Maintenance and inspection may only be performed with a loaded packaging.

Before transport after storage, the condition of all packaging components and the radioactive contents in compliance with all relevant regulations must be established or ensured for the packages. The effects of the radioactive contents on the components of the packaging shall be considered for ageing. Changes of the radioactive contents themselves may affect the safety objectives and shall also be evaluated.

9.3 Ageing management plan

General

The applicant shall define relevant ageing management measures for a package design in form of an ageing management plan (AMP). The preparation of an AMP may be omitted for packagings intended for single use without prior storage in the loaded state. Specifications in the context of periodic inspections may be sufficient in case of packagings intended for repeated use. The measures regarding the AMP shall be presented appropriately and may be integrated into e. g. the QMP. The AMP is based on the specification of the package design according to the certificate of compliance. The AMP should also consider the conditions during operation of the packaging. The aim is to maintain the packaging in a condition that complies with the package design specification to enable its continued operation and ensure its transportability.

The AMP should evaluate the expected ageing mechanisms and ageing effects. For this purpose, parameters resulting from operation, e. g. from the environment (e. g. humidity, temperature, solar radiation), from handling (static/dynamic loads), from design (pressurization, compression, contact of different materials) and from the inventory (radiation, corrosive properties of the contents) shall be identified. Subsequently, relevant ageing mechanisms such as corrosion, wear, embrittlement, radiolysis, or thermal effects are to be derived from the influencing variables. The effect of the ageing mechanisms on the packaging or on individual components/component groups shall then be analysed in detail and ageing effects such as material degradation, changes in strength and plastic deformation shall be identified and evaluated. Particular attention should be paid to components/component groups that are not accessible and replaceable. The applicant shall provide suitable visualization of ageing effects on the component/component group of the packaging, on the inventory or operating condition. Based on the assessment of the ageing effects, the AMP should define measures required for ageing surveillance from the applicant's point of view.

Ageing surveillance program (ASP)

Changes to the design that may affect the package performance during operation shall be controlled by defining suitable measures in the form of an ageing surveillance program (ASP) for packages that are transported after storage in a loaded condition and, if applicable, for components of packaging for

repeated use that are not accessible within the scope of a periodic inspection. These measures shall be included into the documents for use, maintenance, and inspection (e. g. test plans or maintenance and inspection instructions). The ageing monitoring measures are carried out in accordance with the specifications in the use, maintenance, and inspection instructions. For packagings intended for single and repeated use, it may not be necessary to prepare an ASP.

The measures of the ageing surveillance program are intended to detect, monitor, avoid, reduce, and evaluate the effects of ageing. The ageing surveillance program may provide measures for the affected components or component groups as well as for specific ageing mechanisms. Depending on the accessibility of the components/component groups, these can be, for example, measures for regular monitoring of the packaging/packaging unit, periodic inspection, maintenance, repair or the defined replacement of components or component groups. The type and extent of the measures are influenced by the type of use of the packaging/package and the accessibility or replaceability of the components/component groups.

The methods of monitoring should correspond to the state of the art. These may be e. g. visual inspections or non-destructive tests.

9.4 Documentation of ageing management measures

The goal of documenting the measures for ageing management is to ensure the continuous documentation of all relevant measures defined in the documents for the operation of the packaging for the entire service life. The documentation includes e. g. relevant protocols that shall be completed for each packaging/package in compliance with the operating instructions. The consignor is responsible for checking the systematic documentation of the measures described in section 9.3. This may also include the ASP with defined monitoring measures and the resulting protocols and records.

The instructions for use and maintenance including inspections shall contain specifications and responsibilities for the evaluation and documentation of the results of ageing monitoring. Furthermore, instructions shall include measures and responsibilities regarding the participance in the feedback of operational experience. This documentation shall be transparent and comprehensible so that decisions and actions (e. g. replacement or repair of components/component groups) may also be comprehensible in retrospect. The documentation should generally be stored in the test book/inspection logbook or with the corresponding shipping documents.

10 Fees

The fees for assessment and inspection have to paid by the applicant. Fees charged are by BAM are based on the relevant national ordinance Kostenverordnung für Maßnahmen bei der Beförderung gefährlicher Güter (GGKostV)" [15].

11 References

[1] Übereinkommen vom 30. September 1957 über die internationale Beförderung gefährlicher Güter auf der Straße (ADR) (BGBl. 1969 II S. 1489), Anlagen A und B in der Fassung der Bekanntmachung vom 16. November 2021 (BGBl. 2021 II S. 1184), die zuletzt durch die 29. ADR-Änderungsverordnung vom 22. November 2022 (BGBl. 2022 II S. 601) geändert worden ist.

[2] Übereinkommen über den internationalen Eisenbahnverkehr (COTIF), Anhang C – Ordnung für die internationale Eisenbahnbeförderung gefährlicher Güter (RID) vom 9. Mai 1980 (BGBl. 1985 II S. 296) in der Fassung der Bekanntmachung vom 22. April 2022 (BGBl. 2022 II S. 279), die zuletzt durch die 23. RID-Änderungsverordnung vom 3. November 2022 (BGBl. 2022 II S. 555) geändert worden ist.

[3] Europäisches Übereinkommen vom 26. Mai 2000 über die internationale Beförderung von gefährlichen Gütern auf Binnenwasserstraßen (ADN) (BGBl. 2007 II S. 1906, 1908), Anlage in der Fassung der Bekanntmachung vom 10. November 2021 (BGBl. 2021 II S. 1150), die zuletzt durch die 9. ADN-Änderungsverordnung vom 14. Dezember 2022 (BGBl. 2022 II S. 690) geändert worden ist.

[4] International Maritime Dangerous Goods Code (IMDG Code), Amendment 41-22, in der amtlichen deutschen Übersetzung bekannt gegeben im Dezember 2022 (VkBl. 2022 S. 829).

[5] Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße, mit Eisenbahnen und auf Binnengewässern (Gefahrgutverordnung Straße, Eisenbahn und Binnenschifffahrt - GGVSEB) in der Fassung der Bekanntmachung vom 18. August 2023 (BGBl. 2023 I Nr. 227).

[6] Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen (Gefahrgutverordnung See - GGVSee) in der Fassung der Bekanntmachung vom 21. Oktober 2019 (BGBl. I S. 1475), die zuletzt durch Artikel 16 des Gesetzes vom 12. Dezember 2019 (BGBl. I S. 2510) geändert worden ist.

[7] Luftverkehrs-Zulassungs-Ordnung vom 19. Juni 1964 (BGBl. I S. 370) in der Fassung der Bekanntmachung vom 10. Juli 2008 (BGBl. 2008 I S. 1229), die zuletzt durch Artikel 4 der Verordnung vom 7. Dezember 2021 (BGBl. 2021 I S. 5190) geändert worden ist, in Verbindung mit den ICAO Gefahrgutvorschriften (ICAO Technical Instructions).

[8] International Atomic Energy Agency (IAEA), Regulations for the Safe Transport of Radioactive Material, 2018 Edition. Specific Safety Requirements No. SSR-6 (Rev. 1), Vienna 2018.

[9] IAEA SSG-26: Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Rev. 1 (2018 Edition), Vienna: International Atomic Energy Agency (IAEA), 2022.

[10] DIN EN ISO 9000: Qualitätsmanagementsysteme, Grundlagen und Begriffe, November 2015.

[11] DIN EN ISO 9001: Qualitätsmanagementsysteme, Anforderungen, November 2015.

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

[13] DIN EN 10204:2005-01 Metallische Erzeugnisse - Arten von Prüfbescheinigungen, 2005-01.

[14] Specific Safety Guide SSG-66: Format and Content of the Package Design Safety Report for the Transport of Radioactive Material, International Atomic Energy Agency (IAEA), Vienna 2022.

[15] Kostenverordnung für Maßnahmen bei der Beförderung gefährlicher Güter (Gefahrgutkostenverordnung - GGKostV) in der Fassung der Bekanntmachung vom 11. März 2019 (BGBl. I S. 308), die zuletzt durch Artikel 4 der Verordnung vom 28. Juni 2023 (BGBl. 2023 I Nr. 174) geändert worden ist.

Appendix 1 General application requirements

1. Applicant (manufacturer) details

- Address and contact details, including external manufacturing sites, if applicable

2. Application information

- Initial application, recurring application, application for assessment due to changes

3. Packaging information

- Design name
- Package type in accordance with the regulations
- Brief description
- Specifications for permitted contents

4. Information on package design assessment

- Reference to the package design safety report
- Certificate of compliance

5. Additional documents to be submitted (only amended documents if not initial application)

- Packaging-specific QMP (as per section 5)
- Existing certifications of the QM systems
- Other packaging-specific qualifications
- Certification of inspection before commissioning (sample)
- Fabrication and test sequence plan (FPP)
- Instructions for use
- Instructions for maintenance and inspection

Appendix 2 General requirements for creating a Certificate of compliance

- Type of package according to the transport regulations (e. g. IP-2, IP-3, Type A)
- Design name
- Issue date and expiry date, if applicable
- Admissible modes of transport, restriction for transport, if applicable
- A list of applicable national and international regulations, including the edition and the relevant paragraphs of the Transport Regulations
- Reference to the package design safety report
- The following statement: "This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported."
- A description of the packaging incl. an illustration, not larger than 21 cm × 30 cm (may provide online or via QR-Code), of the materials, total mass, and outer dimensions.
- Specification of the design by reference to the drawings/part lists
- Specification of the permitted radioactive contents, including any restrictions on the radioactive contents that might not be obvious from the nature of the packaging. This includes the physical and chemical forms, the activities involved (including those of the various isotopes, if appropriate), amounts in grams, and whether special form radioactive material is present.
- Reference to instructions for use, maintenance, and inspection and further documents, if applicable
- Reference to the applicable ageing management plan, if necessary
- Specification of the applicable management system, under which the package was designed, manufactured, tested, and documented.
- Any emergency arrangements deemed necessary
- Name and address of the applicant or holder of the acceptance certificate of the management system
- Identification and signature of the person responsible for certifying the compliance

Appendix 3 General requirements for creating a Certificate of acceptance

- Design name
- Serial number of the packaging
- Date of issue and expiry date of the Certificate of acceptance
- Reference to the Certificate of compliance
- Declaration that the manufactured packaging complies with the design according to the Certificate of compliance
- Reference to the quality management plan or the management system under which the packaging was manufactured
- Reference to the management system acceptance by BAM
- Name and address of the applicant and, if applicable, manufacturer
- Name and signature of the Authorized inspection representative

Appendix 4 General requirements for instructions for use

The instruction for use shall contain at least the following specifications respectively requirements regarding following points, if applicable:

- Closing
- Permitted contents and masses
- Loading and unloading
- Package fastening during transportation
- Handling
- Requirements for qualification of staff and participating entities
- Applicable work and test instructions
- Work and test equipment to be used
- Specifications for maintenance and inspection, repair measures, replacement of parts/assembly groups including its specifications, if applicable, reference to the instructions for carrying out maintenance and inspection
- Specifications for the ageing management of the packaging
- Periods and course of action in the event of deviations and modifications
- Type and scope of documentation for measures.

It is recommended to hand over the following documents with packaging or to make them available by imprinting a suitable link, e. g. in the form of a QR code:

- Certificate for compliance
- Certificate of acceptance
- Instructions for use
- Instructions for maintenance and inspection, test plans for periodic inspection
- BAM acceptance of the management system and the QMP or reference to the acceptance of the management system

Appendix 5 Requirements for external inspection agencies

General requirements

- The external inspection agency shall be an autonomous organisation or part of an organisation. An organisation as defined by these rules includes quality standard and monitoring associations or individual persons.
- The services of the external inspection agency shall be accessible to the public.
- The external inspection agency shall have a documented management system appropriate to the type and scope of activities to be performed.
- The external inspection agency is committed to comply with the legal requirements including the regulations of BAM-GGR 016.
- The external inspection agency shall perform its inspections as per this rule itself.
- The external inspection agency shall treat knowledge it acquires as part of its inspection's activities confidential.

Organisational requirements

- The external inspection agency, or organisation to which is belongs, shall be legally identifiable.
- An external inspection agency as part of an organisation **shall** be identifiable within the organisation.
- A person responsible shall be appointed for managing the external inspection agency.
- The external inspection agency shall guarantee impartiality.
- The external inspection agency and relevant employees shall not perform activities which could affect their integrity and non-biased judgement.
- The external inspection agency shall be able to provide records of sufficient qualifications, training and experience of each of its experts.

Personal requirements

- The auditors employed by the external inspection agency shall possess adequate knowledge the dangerous goods regulations, of the tests described in this rule and in the QMP as well as of the hazards posed by radioactive materials.
- The experts shall have appropriate knowledge of the respective manufacturing processes and materials.
- The experts shall be able to issue the necessary certificates, logs and reports proving the tests that have been conducted and provide technical statements regarding compliance with the general requirements, based on test results and relevant reports.
- Evidence of the expert's necessary knowledge shall be submitted to BAM before being included in the list of experts of an external inspection agency.

Appendix 6 Requirements for monitoring reports

The external inspection agency shall compile a report about the inspections containing at least the following information:

- Name and address of the contractual partner and monitored production site,
- Packaging designs manufactured in the monitoring period,
- Authorised inspection representative of the manufacturer,
- Date of the inspection,
- Checks conducted during inspection, and their results,
- Deviations concerning packagings, if applicable,
- Checks of compliance of documents and documentation to be handed over with each packaging with the specifications in the QMP (see also section 5.5),
- Any deficits in the management system/QMP, as well as agreed follow-up measures or recommendations,
- Overall evaluation of the inspection regarding compliance with the requirements of the BAM-GGR 016.

Appendix 7 Template for Fabrication and test sequence plan (German: FPP)

Manufacturer: Logo, Name	**Fabrication and test sequence plan** Title	FPP-no., Rev.:	Page: ... of ...
		Ident-no.:	number of units:

Package design name:	Drawing number-No.:	Order-no. H:
Component:	Material:	Order-No. K:

Manufacturing stage no.:	Test stage no.:	Manufacturing/test stage description	Maunfacutring/test specification	Inspection by: H	Inspection by: K	Written proof required	Test certificates H	Test certificates K	Proof / comments (certificate, log, etc.)

Creator	Release of the FPP		Documentation review	
Date, Name	Date, Signature, Stamp	Date, Signature, Stamp	Date, Signature, Stamp	Date, Signature, Stamp

Explanations:
x = Mandatory participation
H = Authorised inspection representative of the manufacturer
K = Applicant