



REVISED GUIDELINE FOR THE APPROVAL PROCEDURE OF PACKAGE DESIGNS IN GERMANY

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1. Introduction

The IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1 [1] are applied in Germany through the implementation of the Dangerous Goods Transport Regulations for class 7 of the International Modal Organisations (ADR, RID, IMDG-Code, ICAO-TI). Based on this the approval procedures for packages designs applied in Germany are in compliance with the provisions of TS-R-1.

The Guideline R 003 [1] issued by the Ministry of Transport, Building and Housing (BMVBW) in 1991 is the basis for the package design approval procedures in Germany. This Guideline has been reviewed and revised to reflect latest developments in the regulations as well as in the regulatory practice. In particular it has been extended to the approval procedures of Type C packages, packages subject to transitional arrangements, special form and low dispersible radioactive material and provides more detailed information to the applicant about the requested documentation. Publication of this revised guideline has been delayed but it is expected to take place in October 2004.

The paper gives an overview about the main parts and provisions of this revised Guideline R 003 with the focus on package design approval procedures.

2. Legal basis and scope

The guideline explains design approval procedures which are subject to competent authority approval according to the dangerous goods transport regulations in Germany (GGVSE for road and rail transport, GGVSee for sea transport, GGVBinSch for inland waterway transport, Luftverkehrs-Zulassungs-Ordnung for air transport). These design approval requirements are consistent with the provisions of TS-R-1 [1].

The guideline applies to all designs for

- Type B(U) packages, Type B(M) packages and Type C packages
- Packages containing fissile material (Type IF, - AF, - B(M)F, - B(U)F, and - CF)
- Packages containing 0.1 kg or more of fissile excepted uranium hexafluoride (H(U)/H(M))
- Special form radioactive material, and
- Low dispersible radioactive material.

It explains the whole approval procedure including application, documentation, evaluation and certification for the various designs and considers certain aspects like validation of foreign package design approvals and package design approvals subject to transitional arrangement. In addition it clarifies the responsibilities of the certificate holder as well as the conditions to use an approved package in practice.

3. Responsibilities

The Federal Office for Radiation Protection (BfS) is the competent authority for

- Type B(U) -, Type B(M) -, and Type C package design approvals, and
- all package designs approvals for fissile material (Type IF, - AF, - B(M)F, - B(U)F, and - CF).

During the approval procedure BfS is responsible to perform assessments on all radiological and nuclear aspects of the package design in particular by own evaluations of shielding and criticality safety. BfS is also competent authority for all shipment approvals including special arrangement but these approval procedures are not within the scope of this guideline.

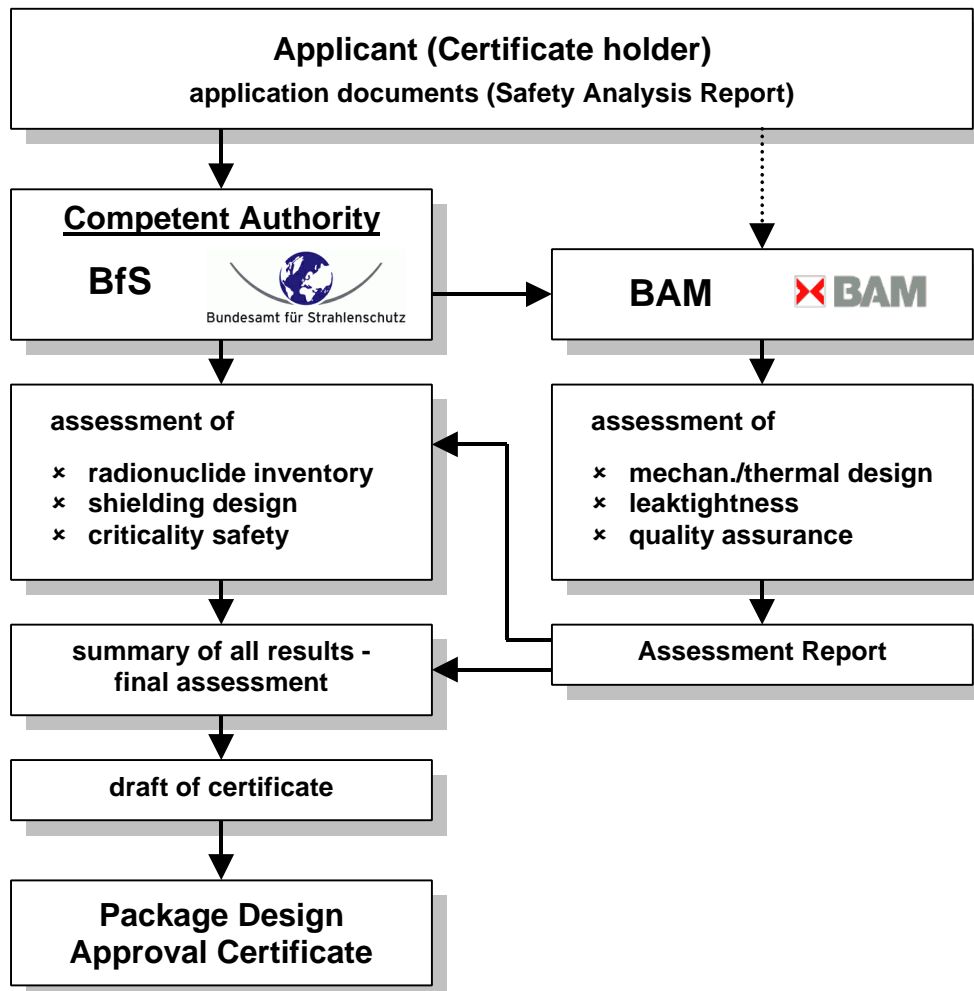
The Federal Institute for Material Research and Testing (BAM) is the competent authority for approvals of

- Packages containing 0.1 kg or more of fissile excepted UF₆ (H(U)/H(M)), and
- Special form and low dispersible radioactive material.

BAM is responsible for the assessment of the mechanical and thermal behaviour of the package design including its tests, if necessary, its leaktightness and quality assurance programme. BAM is also responsible for the quality monitoring of the manufacture and repeated testing of the packagings but these procedures are not within the scope of this guideline.

4. Procedure for package design approval

The following figure provides an overview on the package design approval procedure in Germany.



The applicant who becomes the certificate holder at the end of the process must submit the application containing all requested documents in duplicate to BfS as the competent authority. BfS transmits one set of application documents to BAM for their expertise work. It is also possible to send the application documents in parallel to BAM if this is noticed in the application letter to BfS.

The application documents must be complete before the review and assessment work by BfS and BAM can be started. In principle this date of receiving the complete application documents determines the sequence of application processing.

The review and assessment work by BfS and BAM according to their responsibilities as described under section 3. is done in parallel as far as possible. The results of the expertise work by BAM are stated in a BAM assessment report which is sent to BfS for further use in the approval procedure and to the applicant for information. As requested by BfS part of the BAM report is the verification of the applicant's assumptions used to represent mechanical and thermal deformations and arrangements under normal and accident conditions of transport in the shielding and criticality safety analysis. Based on this BfS can now finish its assessment work on shielding and criticality safety.

Finally all assessment results are summarised by BfS and checked for completeness. If needed, special conditions will be derived from the assessment results which will become part of the package design approval certificate. The certificate will then be drafted and after a final clearance procedure the package design approval certificate will be issued by BfS and sent to the applicant.

In principle the package design approval certificate is valid for 3 years and in some cases up to 5 years. It can be extended by application. For this purpose the certificate holder has to submit documents demonstrating that the package still meets all applicable requirements. This application must also take into account experience feedback from use of the package in particular regarding quality assurance aspects and the effect of new developments of technical rules on the design, if applicable.

Based on the package design certificate the certificate holder is entitled to manufacture packagings. The use of each packaging is allowed if at the time of shipment a valid package design approval certificate exists as well as a certificate of final inspection for this packaging. After 3 years of use in addition a certificate on repeated testing is necessary.

Application documents

The application documents must contain at least the information as stated in the applicable paragraphs of TS-R-1 (paras 805 (b), 807, 810 and 813). The demonstration of compliance with all applicable paragraphs of TS-R-1 for the applied package design has to be submitted in the form of a safety analysis report. This safety analysis report must contain in particular:

- a) Statement on transport modes the package design is applied for and legal basis (edition of transport regulations) of the application
- b) Detailed description of the proposed radioactive contents including, if applicable
 - nuclide(s) / nuclide mixture
 - activity and mass
 - physical and chemical state, geometrical form and arrangement, irradiation data, construction materials
 - nature of radiation emitted
 - heat release
 - mass of fissile material
- c) a reproducible illustration (max. 21 cm x 30 cm) showing the make-up of the package with maximum dimensions and package masses (empty and loaded)
- d) a detailed description of the design and its components by complete engineering drawings, parts lists, material specifications, and descriptions of:
 - package concept in total
 - packaging body and packaging inserts
 - containment system with its components
 - shielding components
 - confinement system to guarantee subcriticality for fissile material
 - shipment concept including construction components necessary for safe handling, securing in or on the conveyance and transshipment (change of transport mode)
 - protection against corrosion and contamination
 - shock absorbing components
- e) safety demonstration showing compliance with each applicable requirement of TS-R-1. Its structure should follow the structure of the respective paras in TS-R-1. This demonstration must include the following main areas:
 - mechanical safety analysis for routine, normal and accident conditions of transport for:
 - components of the containment system
 - components of the radiation shielding
 - components of the confinement system
 - lifting and handling attachments
 - thermal safety analysis for routine, normal and accident conditions of transport for:
 - components of the containment system
 - components of the radiation shielding
 - components of the confinement system
 - compliance with release criteria for normal and accident conditions
 - compliance with dose rate criteria for normal and accident conditions
 - criticality safety analysis for routine, normal and accident conditions of transport in case of fissile material.
- f) quality assurance programme including all necessary instructions for use, maintenance and repeated testing of the package as well as for operations/procedures during transport like transshipment and in-transit storage.

- g) in the case of an application for a Type B(M) or Type B(M)F package design additional information as described in para 810 of TS-R-1.

5. Procedure for validation of foreign package design approval

The approval procedure is basically the same as described in section 4. BfS as the competent authority is responsible for the whole procedure. The applicant must submit the application documents in the same way as outlined above. The review and assessment work by BfS and BAM follows also the same procedure but the kind and extent of review and assessment is defined by BfS depending on the type of package design approval and the specific design.

After finishing the review and assessment work with positive results the validation certificate is issued by BfS according to the same procedure as stated in the section above. The validity period of the German validation certificate is at most the same as defined in the package design approval certificate of the country of origin. The German validation certificate is only valid as long as a valid package design approval certificate of the country of origin exists.

Application documents

The application must contain the following documents:

- a) copy of the original package design approval certificate
- b) German translation of the original package design approval certificate
- c) a reproducible illustration (max. 21 cm x 30 cm) showing the make-up of the package with maximum dimensions and package masses (empty and loaded)
- d) the complete safety analysis report
- e) the quality assurance programme including all necessary instructions for use, maintenance and repeated testing of the package as well as for operations/procedures during transport (including transshipment and use of various conveyances) and in-transit storage
- f) German translation of the instructions for use
- g) additionally, in the case of an application for a Type B(M) or Type B(M)F package design information as described in para 810 of TS-R-1
- h) additionally, in case of an application subject to transitional arrangements (paras 816, 817 of TS-R-1) a statement on which requirements of the current transport regulation the applied package design does not comply with.

6. Procedure for special form and low dispersible radioactive material approval

The application for special form or low dispersible radioactive material (LDM) approval has to be submitted to BAM as the competent authority. In case of LDM approval BAM transmits one set of application documents to BfS for their expertise work. It is also possible to send the application documents in parallel to BfS if this is noticed in the application letter to BAM.

The application documents must be complete before the review and assessment work by BAM and, if applicable by BfS can be started. In principle this date of receiving the complete application documents determines the sequence of application processing.

BAM is responsible for the assessment of the mechanical and thermal behaviour of the design, its leaktightness and quality assurance programme. In case of LDM approval BfS performs the assessment of the radiological properties regarding compliance with dose rate criteria. The results of the expertise work by BfS are stated in a BfS assessment report which is sent to BAM for further use in the approval procedure and to the applicant for information.

After finishing the review and assessment work with positive results the special form or LDM approval certificate is issued by BAM. In general this certificate is valid for 5 years.

Application documents

The application documents must contain at least the information as stated in para 803 of TS-R-1. They must include in particular:

- a) name of the manufacturer of the design

- b) identification of the design
- c) detailed description of the radioactive material including nuclide/nuclide mixture, activity and mass, physical and chemical state and nature of radiation emitted
- d) detailed description of the design by complete engineering drawings, material specifications and markings
- e) scope of application
- f) performed tests to demonstrate compliance with requirements (e.g. ISO-test reports)
- g) quality assurance programme

7. Some aspects of package design approval practice

Experience has shown that such a guideline on approval procedures is very helpful to applicants and users in practice. It is expected that the revised guideline will further improve the effectiveness and transparency of the approval procedures in the future because more detailed information on kind and extent of requested application documents will be available.

In particular the request to submit a document demonstrating compliance with each applicable requirement of TS-R-1 (see item 4.e)) has been shown to be very helpful for the applicant to work out the safety analysis report as well as to the competent authorities to perform the assessment work. This can be done e.g. by a list of paragraph numbers of TS-R-1 applicable to the type of package design to be approved. Such a list with reference to the documents or other justifications providing demonstration of compliance with the provisions of these paragraphs improves quality assurance and compliance assurance aspects of package design approval procedures considerably.

Another aspect which is important for package design approval procedures in practice is the question how to handle modifications to a package design? It is clear that any safety related modification has to be applied by the applicant and to be approved by the competent authority which will result in a revision of the package design approval certificate following the procedures as described above. But there are many non-safety related modifications leading to changes in the drawings of the design. To handle such changes without to revise the whole package design approval certificate a "design type list" or the procedure of a "certificate of modification" has been introduced in the package design approval procedure in Germany [4].

The "design type list" contains the actual and all previous (if needed) revisions of the main parts list which covers all drawings and sub part lists of the approved design. In this way the design is completely defined with all details. The "design parts list" is part of the package design approval certificate but can be revised separately without revision of the whole certificate. The procedure of a "certificate of modification" is another way to handle small changes without revision of all related drawings and type lists immediately.

Both procedures are subject to clearance and approval by BAM and BfS. In this way the competent authority is informed about any change to the design at any time.

Good experience has been made with these procedures. On the one hand they allow to react quickly on practical needs for changes to the design by the certificate holder without to revise the package design approval certificate and on the other hand they guarantee that the actual and complete status of the package design is available all the time in compliance with the package design approval certificate.

References

- [1] Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), IAEA Safety Standards Series No. TS-R-1, Vienna 2000
- [2] Richtlinie für das Verfahren der Bauart-Zulassung von Versandstücken zur Beförderung radioaktiver Stoffe - R 003 -, Verkehrsblatt des BMVBW, Heft 4, 1991
- [3] Richtlinie für das Verfahren der Bauart-Zulassung von Versandstücken zur Beförderung radioaktiver Stoffe, von radioaktiven Stoffen in besonderer Form und gering dispergierbaren Stoffen - R 003 -, to be published in October 2004
- [4] Boerst, F.-M., Nitsche, F., Package design approval certificate specification – How specific is specific enough?, Proceedings of the International Symposium on Packaging and Transportation of Radioactive Material (PATRAM 2001), Chicago, 3-7 September 2001