NUCLEAR CARGO + SERVICE

Issued by: Section AT

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Development of Packaging Concepts

Owner of process: Manager AT

Distribution: GF, AT, BSR, KBU, SP, ST-S, TK	
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Contents

1 Object of instructions, responsibilities

These instructions describe the basic steps when developing packaging concepts for radioactive materials. They are valid fort he planning of packagings and the approval of packages.

For partial proceedings, the instructions mentioned in Attachment A1 are valid.

Total responsibility for the development of packaging concepts is the Area Manager AT, who thus is the owner of the process.

The matrix in Attachment A2 describes responsibilities, competences and participations of the involved sections/staff units.

2 Legal frame

2.1 Basic principles

Conditions for the traffic carriers road, rail, air and water defined in the regulations contained in the „Regulations for the Safe Transport of Radioactive Material, TS-R-1, IAEA, Vienna“ or international and national regulations derived from these must be respected.

The following regulations are relevant in Germany:

Cross-border valid regulations:

TS-R-1, ADR, RID, IMDG-Code, IATA-Dangerous Goods Regulations, ICAO-Technical Instructions

National Laws and Ordinances:

GGBefG, GGVSEB, GGVSee

The „Guideline for the Procedure of Qualification Approval of Packages for Transporting Radioactive Materials, Radioactive Materials in Special Form and Slightly Dispersible Radioactive Materials – R 003 „ is decisive for the approval of packages.

For quality assurance during the development, fabrication and operating of packagings for radioactive materials, the „Technical Guideline concerning Quality Assurance Measures (QM) and Quality Supervising Measures (QÜ) for Packagings for Transporting Radioactive Materials – TRV 006 –„ must be observed for packagings which must be submitted to inspections, and the "Quality Assurance Measures for Radioactive Material Transport Packagings of Designs subject to Approval" must be observed in the case of packagings subject to approval.

2.2 Classification of packages according to R 003

Packages are classified according to R 003 as packages subject to approval and such which are not.

Packages subject to approval:

Type B(U), Type B(M) and packages for fissile products.

Packages which are not subject to approval:

Type A, IP-3, IP-2, IP-1, exempted packages

2.3 Classification of packagings according to TRV 006 and BAM-GGR 011

Quality supervision of packagings is defined as follows according to TRV 006 and BAM-GGR 011:

Quality supervision of exempted packagings and industrial packagings of Type IP-1:

Packagings of exempted packages and industrial packages of Type IP-1 are exempted from quality supervision.

Quality supervision of packages subject to inspections

Insofar as no standardized supervision programs according to these guidelines are published in the official and communications gazette of BAM, these are subject to preliminary release by BAM.

Quality supervision of packages subject to approval

Packagings of packages subject to approval or Type B(U) and Type B(M), as well as packages with fissile contents, are subject to quality supervision according to BAM-GGR 011 during layout, testing, fabrication and operation.

3 Interfaces

Essential interfaces from the process „Development of Packaging Concepts" to other QM systems or QM processes will result

A) Internally to

- Total system
- Process „Class 7 Transports"

B) Externally to

- BfS
- Foreign Approval Authority (e.g. ASN)
- BAM
- TÜV
- Manufacturer (supplier)
- Customers

Competences are defined according to

A) internal interfaces

In the QM systems documentation (QM Manual, Process instructions)

B) external interfaces

- for authorities and experts to a large extent through regulations
- for customers and suppliers
  - valid in general in the QM system documentation

- project specific in the single contracts and the corresponding documents

4 PROJECT QUALITY

4.1 Causes for development projects

The causes for development projects (new developments or changes) may be

- changes of Regulations
- market requirements
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4.2 Compiling of basic data for development

Section AT compiles the data presently available for the rough concept. These data include information concerning the physical and chemical constitution of the radioactive materials, and irradiation and decay data in case of irradiated material.

It is at present in general not possible or too expensive to obtain a more detailed requirement profile.

4.3 Rough concept

Section AT works out rough concepts which will permit to evaluate the technical en economical feasibility of the development project. The rough concepts are documented by means of concept drawings and descriptions.

4.4 Evaluation of rough concepts by internal/external customers

Rough concepts are explained to both internal and external customers. In case of negative evaluation of the feasibility (technical and/or economical), the development project is stopped at this stage.

4.5 Informal presentation of rough concepts to BfS/BAM

Developments of packages subject to approvals are presented informally to BfS and BAM, especially when new concepts are used for the development. The project manager will draw conclusions from these informal presentations as to the feasibility of the development project as far as the possibility of approval is concerned.

4.6 Decision concerning continuation of project

Depending on the estimated project costs, and on the resources required to carry out the project, the project manager will prepare a decision document (compilation of the information obtained during the rough concept phase), based on the results of the evaluation through internal or external customers and, if this is the case, on the informal contacts with BfS/BAM. The decision document will include the following indications for projects, for which a decision must be made by GF, due to overall cost estimations or the necessary resources:

- Favored rough concept
- Justification of the selection of the favored rough concept
- Risks during realization
- Estimation of costs
- Duration of the development project
- Required personnel for the development project

For smaller projects, for which a decision may be made by the project manager himself, the decision document includes the collection of all documents prepared during the rough concept phase. This also holds for projects for which the area manager AT makes the decision, unless the area manager AT requires a summarizing decision making document in order to make his decision.

The decision making document is checked and decided upon by the project manager, the area manager AT or GF, depending on the estimated overall costs. In case of negative decision, the development project will be stopped at this phase.

In the case of projects for external customers, a positive decision will be documented by means of a corresponding offer, signed according to the valid rules for signatures. In the case of internal projects, a positive decision will be documented by opening a development/investment product unit.

5 Design Quality

5.1 Requirement specification

A requirement specification will be developed on the base of preliminary legal requirements and of customer requirements, taking into account knowledge gained during the rough concept phase. This requirement specification consists of:

- The determination of the traffic carriers for which the package must be approved;
- The specification of the radioactive material (physical and chemical composition, if applicable irradiation history and cooling times, admissible contents per package, if applicable, supplementary dangerous characteristics);
- Specification of conditions of utilization at the customer's (admissible maximum dimensions and masses, auxiliary equipment which must be used, e.g. suspension gear, measures necessary to avoid contamination).

The requirement specification will be presented to internal/external customers by way of information. Release through customers only is possible for certain partial aspects, because as a rule, customers do not have the necessary knowledge to be able to evaluate the requirement specification.

5.2 Detailed specification from rough concept to fine concept

Based on the requirement specification, the rough concept is worked out in detail to the point where an evaluation of the concept is possible insofar as the fulfillment of legal regulations is concerned. In this phase, design and calculations are refined iteratively to the point where agreement is reached between design and legal regulations.

The results of this phase of development are project drawings describing the essential details of the packaging.

5.3 Safety report

Starting from the project drawings, the safety report is worked out on the base of the requirement specification. It is verified in this report that the package fulfils legal regulations. For this purpose, the safety report contains a description of the packaging and of the contents, as well as analyses of the mechanical and thermal behavior, of tightness, of screening and, in case of fissile materials, of criticality safety, taking preliminary legal requirements into account.

Analytical methods or tests may be used for the analysis of the mechanical and thermal behavior of the packaging. Insofar as empirical tests are used for verifying the behavior, a rough analysis will be introduced into the safety report, and a test program as an attachment.

Furthermore, the safety report includes all documents required for quality assurance during fabrication and operation. These are the fabrication specifications, handling and maintenance instructions, the plan of periodic inspections, as well as all secondary documents mentioned in these documents.

Parallel to the working out of the safety report, the drawings of the packaging will be completed according to the results obtained by the safety report.

The result of this phase of development is the complete safety report with design drawings, describing all the details of the packaging required for the fulfillment of legal regulations and of the requirement specification.

5.4 Approval requirement

The approval requirement is filed with BfS in the case of packages subject to approval. The approval requirement defines the traffic carriers which must be mentioned in the approval, the type of package and, if applicable, the criticality safety index and the contents, and contains the safety report as an attachment. A copy of the approval requirement is also presented to BAM together with the attachment.

As a rule, internal and external customers only will receive one copy of the approval requirement without attachment. The attachment will only be handed over to external customers, when this is expressly specified in the development contract.

5.5 Packages not subject to approval

In the case of packages not subject to approval, the project manager will work our an NCS approval based on the safety report. This NCS approval is checked by the Approval Group and released through ST-QS.

In the case of packages subject to approval, the manufacturer specification and the drawings are presented to BAM, which will release the quality assurance measures.

5.6 Production drawings

Production drawings will be worked our in this phase, based on design drawings, insofar as no definitive production drawings were worked out with the safety report. These production drawings may be worked out by Section AT, insofar as they have sufficient knowledge and experience concerning production processes and possibilities.

If experience concerning production processes and possibilities is not sufficient, the manufacturer of the packaging may be entrusted with the working out of the production documents.

5.7 Testing program

Testing programs are set up for the development projects, for which technical safety characteristics must be verified by means of practical tests. This may be due to technical causes (non existent or not sufficiently validated analytic procedures) or to economical reasons (the costs for application of analytic processes are higher than verifications by empirical tests).

The test program contains the following essential parts:

- Description of the test objective
- Description of the test model, together with the justification of deviations as compared to the original
- Definition of tests and test sequences, together with a justification for the selection of the tests and test sequences
- Preliminary conditions for measures of verification of the test objectives (instrumentation, control and auxiliary drilled holes, etc.)
- Preliminary conditions for the implementation of tests – preparation, realization, controls after the tests –
- Preliminary conditions for the evaluation and documentation of the tests
- Determination of responsibilities

In the case of packages subject to approval, the test program will be released by BAM.

5.8 Tests

Tests with packagings for packages subject to approval are carried out by BAM at their drop test facilities, after which they are evaluated and documented.

Tests with packagings for packages not subject to approval may be carried out by NCS or the manufacturer of the corresponding packaging component.

5.9 Revision of the safety report

During the approval procedure, it may become necessary to carry out revisions of the safety report,

- Due to the introduction of tests results,
- Due to supplementary requirements from BfS or BAM
- Due to changes of legal regulations during the approval procedure (the duration of approval procedures may last several years)

5.10 Approval

The documents defining the design model of the package are mentioned in the approval. These are the safety report and the production drawings. Furthermore, he handling instructions and the plan for periodic inspections are explicitly mentioned. These documents are thus part of the approval.

The approval is the result of the development of a packaging concept.

When the development is carried out on order of an external customer and NCS has not been issued an order for the delivery of the packagings or for carrying out maintenance services and periodic inspections, the process is successfully finished at this stage.

6 FABRICATION/ACQUISITION OF PACKAGINGS

6.1 Fabrication/acquisition

NCS do not produce packagings by themselves. This is assured by manufacturers selected by NCS, who are in the list of qualified suppliers or who were entered into this list before the order was placed. The definitions of the packaging manufacturer's specification and the requirements of BAM-GGR 011 or respectively TRV 006 are valid for this selection.

6.2 Acquisition documents

The manufacturer's specification, drawings and the instructions mentioned in the manufacturer's specification are part of the acquisition documents. Furthermore, the acquisition documents (inquiry, order) include indications concerning the number of packagings which must be delivered, terms of delivery, prices and other commercial agreements.

6.3 Preliminary checking documents

The manufacturer will work out the preliminary checking documents, based on the manufacturer's specification and the drawings of the packaging:

- List of materials,
- Fabrication and control follow-up plan (in part also named construction control follow-up plan, according to the manufacturer's choice),
- Welding plan,
- If applicable, completion drawings (e.g. forging drawings).

The manufacturer hands over the preliminary checking documents to NCS before production begins. The NCS representative in charge of acceptance will check the agreement between preliminary checking documents with the preliminary requirement documents in the acquisition documents. The NCS representative in charge of acceptance will release preliminary checking documents, insofar as no deviations are found.

When deviations are found, the person in charge of acceptance will check the reason for the deviation, involving the project manager, and will initiate corrective measures, if this is applicable. The procedure is as follows:

- Corrective measures for small deviations, such as typing errors, additions for clearing matters, single supplementary entries or deletions may be carried out by means of manual entries and apposition of a counter stamp.
- Larger corrections are carried through correction of the preliminary checking documents through the manufacturer.

In case of packages subject to approval and of packages which must be checked, the preliminary checking documents are presented to BAM for preliminary checking. In case of packages subject to approval, BAM will appoint the BAM expert (TÜV Rheinland/Berlin-Brandenburg), imparting him the order to carry out the preliminary checking of the documents.

Once the preliminary checks have been completed, NCS will be handed back the inspected documents and will hand on the original version of the latter to the manufacturer. The original documents subject to preliminary checking constitute the documentary base for the manufacturing of the packagings.

6.4 Supervision during fabrication

The supervision of fabrication through NCS is settled in the preliminary checking documents. The checking steps are carried out under the responsibility of the person responsible for acceptance appointed by NCS. Implementation of the supervising steps is documented in the preliminary checking documents and, insofar as necessary, in the corresponding records.

Insofar as the checking steps require supervising through a locally responsible expert, the latter will be appointed through NCS. The expert must be mentioned in the SH list of experts accepted by SB. If supervision through

a BAM expert is required during the checking steps, the project manager will appoint corresponding dates, in agreement with the manufacturer.

6.5 Acceptance test

The acceptance test is carried out at the manufacturer's premises, insofar as no other agreements were made in the acquisition documents. The extent of the acceptance test is settled in the acquisition documents. Once the acceptance test was successfully carried out, the NCS member responsible for acceptance will release delivery.

6.6 Documentation

Once the acceptance tests were carried out, the manufacturer will put together the documentation according to the preliminary instructions indicated in the acquisition documents and make copies of them before handing them over to NCS. NCS will keep these documents according to the requirements of the NCS QM system.

7 UTILIZATION OF PACKAGINGS

7.1 Selling packagings to external customers

When packagings are sold to external customers, responsibility is transferred to the latter. In this case, NCS will supply the corresponding cask check books together with the packagings. In case of packages subject to approval, NCS will furthermore require a written assurance from the external customers that they or other users of the packagings will register with BfS as users of the packagings and confirm that they have received the cask check books as well as all pertinent instructions.

The duties of NCS concerning the actualization of packaging specific instructions and of the approval, or if applicable, maintenance and periodic inspections, are settled in the purchase contract.

7.2 Utilization of packagings through NCS

Any section of NCS which disposes of accordingly trained or experienced personnel is entitled to use the packagings. During utilization, the approval and the instructions contained therein must be observed.

7.3 Return of experience

Knowledge obtained during the utilization of the packagings must be communicated to the person appointed by NCS for acceptance by the user. External users must be committed in writing to observe these measures. Dealing with defects found during the utilization of the packagings is settled in corresponding instructions (see Attachment A1, “List of Accompanying Valid Instructions”).

7.4 Periodic inspections

The terms of periodic inspections are also mentioned in the approval or in the documents mentioned therein. These periodic inspections must be carried out according to requirements in the named documents. In the case of packagings which will be sold, it will be expressly pointed out to the purchaser that the documents required for periodic inspections must be available during the inspections. The inspections are carried out under the responsibility of the person appointed for acceptance through NCS, and documented in the mentioned documents according to the preliminary requirements. In case of packages not subject to approval, the certification of carried out inspections will be issued by the person appointed for acceptance through NCS or respectively through an external acceptance organization appointed by the latter.

In case of packages subject to approval, periodic inspections will be performed in presence of the BAM expert. The latter will be invited to assist in the inspections by the project manager. The certifications for inspections carried out are issued by the BAM expert.

In the case of packages with original German approval, copies of the certifications for inspections carried out will be sent to BfS and BAM. The original document is part of the cask check book.

List of accompanying valid instructions

Instruction No.	Title
AA-V-89-02	Working out drawings
AA-V-89-03	Working out and checking deviation reports
AA-V-89-04	Working out and checking documentations
AA-V-89-06	Working out and checking preliminary checking documents
AA-V-89-07	Working out of documents
RL-Q-95-02	Communication and evaluation of errors
RL-Q-95-01	Planning and implementation of corrective measures

Comment: special instructions (e.g. cask specific handling and maintenance instruction, instructions for inspections, etc.) are not entered into this list. A data base set up by Section AT contains an overview of all NCS instructions.