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Swiss Federal Nuclear Safety Inspectorate ENSI



## **Guideline for the Manufacture and Use of Packaging of Radioactive Material**

**Quality Management Guideline for the Manufacture and Use  
of Packaging for the Transport of Radioactive Material**





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**Federal Office of Public Health FOPH**

# Quality Management Guideline for the Manufacture and Use of Packaging for the Transport of Radioactive Material

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## 1 Introduction

The Swiss Federal Nuclear Safety Inspectorate (ENSI), the Federal Office of Public Health (FOPH) and the Swiss Accident Insurance Fund (Suva) are the supervisory authorities for the transport of radioactive material in Switzerland. In their capacity as supervisory authorities, they issue this guideline which specifies the legal requirements and is intended to provide assistance for the supervised parties.

## 2 Subject and scope of validity

This guideline applies to packaging for the transport of radioactive material. The scope includes packages subject to mandatory testing and inspection which do not require approval:

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

and also packages subject to mandatory approval:

- Packages of Type C, B(U), B(M) for radioactive material,
- Packages of Type CF, B(U)F, B(M)F, AF and IF for fissile material and
- Packages of non-fissile uranium hexafluoride or of uranium hexafluoride which is exempted from the requirements for fissile material (Type H(U), H(M)).

The specifications in this guideline may also be applied as appropriate to material subject to mandatory approval:

- Radioactive material in special forms,
- Low-dispersible radioactive material and
- Fissile material.

The purpose of this guideline is to describe the measures required in order to comply with the quality assurance requirements stipulated in the regulations cited in section 3. Specific reference is made to sub-section 1.7.3 of the European Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR). The measures comprise design, manufacture, testing, documentation, use, maintenance and inspection.

The guideline provides recommendations for implementing the requirements stated in the regulations cited in section 3. These recommendations are intended to provide assistance for those involved in performing functions in connection with the manufacture and use of packaging for radioactive material (the designer, manufacturer, owner or user), and they have no binding effect. However, the measures set forth in this guideline are based on internationally recognised quality assurance standards, so their use is also recommended for this reason.

In addition to general quality assurance measures (section 5), this guideline includes specific measures for the designer (section 6), the manufacturer (section 7), the owner (section 8) and the user (section 9), so it is addressed to the parties performing key functions during the manufacture and use of packaging for radioactive material. Sections 6 to 9 are each structured in the same way: they start with an outline of the tasks of the party performing the function in question (designer, manufacturer, owner or user) followed by a list of the main products, documents and reference materials for the relevant sub-process. The third section deals with interactions, including the exchange of documentation in particular, while the fourth section focuses on the respective supervisory measures. A distinction is drawn between packages subject to mandatory testing and inspection and those subject to mandatory approval in compliance with a *graded approach*, especially in connection with the supervisory measures.

In keeping with the structure of this guideline, it is sufficient for an enterprise only to take note of the recommendations on the specific measures for the functions it performs. If multiple functions are performed by one enterprise (e.g. those of designer and manufacturer or owner and user), the sections



corresponding to those functions should be noted. In a case of this sort, simplifications will also result in respect of the required interactions and also, in some cases, as regards the documents to be drawn up

The measures set out in this guideline regarding the design, manufacture, testing, documentation, use, maintenance and inspection of packaging for radioactive material are valid for the national territory of Switzerland. Aspects of the cross-border use of such packaging are covered in section 11.3.

### **3 Legal basis**

The guideline is based on the following legal provisions:

#### *General*

IAEA Specific Safety Requirements SSR-6, *Regulations for the Safe Transport of Radioactive Material*

#### *Road*

European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)

Ordinance on the Carriage of Dangerous Goods by Road (SDR, SR 741.621)

#### *Rail*

Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)

Ordinance on the Carriage of Dangerous Goods by Rail and Cableway (RSD, SR 742.412)

#### *Air*

International Civil Aviation Organization (ICAO), Technical Instructions for the Safe Transport of Dangerous Goods by Air

Ordinance on Air Transport (LTrV, SR 748.411)

#### *Inland waterways*

European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)

Ordinance of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) on Implementing the European Agreement on the International Carriage of Dangerous Goods by Inland Waterways (SR 747.224.211)

#### *Sea*

International Maritime Dangerous Goods Code Class 7 (IMDG)



## 4 Definitions of terms

This guideline makes use of terms from dangerous goods regulations in particular, which can be consulted in sub-section 1.2.1 ADR/RID. In addition, the following terms are used:

### (1) Acceptance

Acceptance denotes the testing and inspection of packaging after the end of its manufacture. A successful acceptance test is the condition required for subsequent commissioning. The time of the successful acceptance determines the start of any applicable maintenance cycles.

### (2) Acceptance officer

An individual with proven expertise and independence who is commissioned to conduct or accept supervisory inspections and tests.

### (3) Acceptance certificate

The acceptance certificate states that, on the basis of the tests carried out, the manufactured packaging corresponds to the design specification on which the test was based.

### (4) Deviation

A deviation is non-conformance of the actual condition with the specified target condition, ascertained during or after the relevant manufacturing step or during use. A deviation is documented in a **deviation report**.

### (5) Deviation report

A deviation report is the overall designation (generic term) for deviation reports and modification requests.

### (6) Modification

A modification is an intentional deviation from the specified target condition that is planned for one or several packagings of one design prior to manufacture. A modification is documented in a **modification request**.

### (7) Audit

Initial and recurring (periodic) review of quality assurance measures on the basis of written documents, interviews and tours of inspection of the enterprise. The purpose of the audit is to verify the suitability and implementation of quality assurance measures. Audits may relate to all activities or to specific processes.

### (8) Design

Conceptual planning, calculation and structural design of packaging.

### (9) Certificate of suitability

Declaration that the design of packaging subject to mandatory testing/inspection meets the requirements imposed on it by the provisions of dangerous goods regulations.

### (10) One-way packaging

Packaging which is used to transport radioactive material to the recipient on one occasion and which is no longer used to package radioactive material after the radioactive material has been removed (or is only used for this purpose after it has again undergone all the necessary tests).

### (11) Hold point

Manufacture must be halted until all parties have successfully completed their tests and inspections and have signed the production and sequential test and inspection plan (FPP). If a written declaration of waiver is available, production may be continued.

### (12) Commissioning

Commissioning is the term used to designate the circulation or first use of packaging, and it may be postponed in relation to the acceptance until after manufacture has been completed.

### (13) Witness point

Manufacture must be halted until the invitation date. After the invitation date, manufacture can be continued. There is no requirement for a written declaration of waiver.





(14)Package subject to mandatory testing/inspection

Packages subject to mandatory testing/inspection are of Type IP-2 and IP-3 and Type A.

(15)Monitoring inspection

Inspection of quality records and actual inspection/testing of packaging to determine compliance with the quality management plan and the manufacturing documents.

(16)Use

The use of packaging comprises, in particular, the tasks of the consignor, carrier, consignee, packer, filler and unloader.

(17)Maintenance

Maintenance denotes planned inspections and repairs to packaging, including periodic tests and inspections in particular.

(18)Maintenance instructions

Maintenance instructions contain a description of planned maintenance for a design type and define the respective intervals between inspections or tests.

(19)Maintenance certificate

Certificate to confirm successful completion of maintenance. In particular, the certificate confirms that the packaging continues to conform to the design specification.

(20)Approval

By issuing an approval, the responsible authority declares that a design subject to mandatory approval meets the requirements set for it by the provisions of dangerous goods regulations.

(21)Package subject to mandatory approval

Packages subject to mandatory approval are those of Type B, C and H and packages of Type CF, B(U)F, B(M)F, AF and IF for fissile material.

(22)Material subject to mandatory approval

Material subject to mandatory approval comprises special form radioactive material, low-dispersible radioactive material and fissile material.



## 5 General quality assurance measures

### 5.1 Quality management system (QM system)

The QM system governs the following aspects of quality assurance (which are principally system-related) and must be documented in the form of a process description:

- Enterprise-specific structural and procedural organisation,
- Responsibilities, methods, processes and resources for carrying out quality management,
- Collaboration of the players,
- Collaboration with the responsible authorities and acceptance officers and
- Qualification/audit of manufacturers and suppliers.

When implementing quality assurance, it must be ensured that the tasks of each involved party are clearly defined, and that the demarcations between the parties are stipulated and described. This includes the users.

QM systems that are already certified (e.g. in compliance with the ISO 9000 series [1] [2]) are suitable if the scope of certification also includes the manufacture and/or use of dangerous goods packaging in class 7 as per ADR/RID. Adaptations to the requirements for packaging may be necessary [3]. This guideline must be taken into account as appropriate.

### 5.2 Quality management plan (QM plan)

The QM plan governs the following aspects of quality assurance, which are principally related to the packaging. The QM plan must be drawn up in writing and must refer to one or more types of packaging, which must be named in the QM plan.

- Design, design test, permitted content, list of documents,
- Procurement of materials, components,
- Manufacture of packaging,
- Quality controls, measures in case of modifications and deviations,
- Acceptance tests and their documentation, issue of certificates,
- Instructions on operation, maintenance and periodic testing,
- Issue of documents for forwarding to the owner and/or user,
- Keeping cask documentation and
- Arranging maintenance measures such as periodic tests and inspections.

### 5.3 Qualification/audit

Audits include verification of the following aspects in particular:

- Processes,
- Working procedures and
- Documents.

The reference documents for audits are the QM system and the QM plan.

In order to conduct audits, all necessary quality record documentation must be made accessible to the appointed or responsible auditors, and samples of packaging or components must be made available where appropriate. For any tests that may be needed, equipment and measuring instruments must be made accessible to the auditors, unless the tests are carried out with equipment or measuring instruments belonging to the auditors themselves.



The auditors must draw up a report on the audit containing at least the following information:

- Name and address of the auditee,
- Audited area or sub-area,
- Types of packaging affected by the monitored period,
- The auditee's quality officer,
- Date of the audit,
- Tests/inspections carried out during the audit and their results,
- Any deviations in respect of packaging,
- Any deficiencies in the QM system/QM plan, with agreed follow-up measures/recommendations and
- Overall assessment of the results of the audit.

The original of the audit report must be signed by the auditor and the auditee's quality officer, and it remains with the auditee. Audit reports must be kept by the auditee for at least 10 years and must be submitted to the responsible authority on request.



## 6 Duties of the designer

### 6.1 Design

#### 6.1.1 General procedure

The designer is responsible for the design of the package. In addition to the requirements arising from ADR/RID 6.4, the design must also be based on all parameters and features (such as permitted quantity, physical, chemical and radiological characteristics of the content, operational and testing requirements for the packaging, safety-related characteristic and functional parameters of the packaging, its components and materials) which must be taken into account in order to attain the protection objectives defined by dangerous goods regulations, namely:

- Shielding,
- Tightness and integrity,
- Heat dissipation (as necessary) and
- Guarantee of sub-criticality (as necessary).

The design is supported by analytical or numerical calculations and experimental investigations, insofar as necessary. These serve the purpose of determining or verifying characteristics of components or materials.

The design must also be based on requirements arising from any other regulations, standards and guidelines that may need to be met. Attention should be paid to the ability to test significant safety characteristics in order to attain the dangerous goods protection objectives.

Anomalies reported by the manufacturer or owner during the manufacture and/or use of packaging must be assessed and taken into account when drafting further designs, as appropriate to the purpose.

#### 6.1.2 Classification of components

Both for the design work and all downstream tasks in the course of manufacture and use, it is helpful to classify components and/or component parameters on the basis of their importance to safety. The key factor for this classification should be the function in relation to the protection objectives mentioned in section 6.1.1. The classification may, where appropriate, be restricted to areas or characteristics of a component or to steps in its manufacture.

In principle, the following classification is recommended:

**Level 1:** all components and/or component parameters which directly guarantee the aforementioned protection objectives.

**Level 2:** all components and/or component parameters which indirectly guarantee the aforementioned protection objectives.

**Level 3:** all components and/or component parameters which are not included in levels 1 or 2.

Further grading of the requirements for components in the same classification levels may be implemented on a design-specific basis.

Safety reasons may make it necessary to assign components to a higher class (e.g. load attachment points for transport casks that are moved in nuclear power plants). Consideration must also be given here to function-relevant relationships between individual parts or components.



### 6.1.3 Design verification

#### All package designs

A package design verification must be carried out in order to verify compliance with the regulations stipulated by dangerous goods regulations. This consists of experimental and/or calculative investigations for which prototypes, series samples or suitable models may also be used. Compliance with the regulations specified by dangerous goods regulations is required for this purpose.

Compliance with the requirements specified by dangerous goods regulations for the relevant design must be documented in the form of a safety report or test report after the design verification is completed [4] [5]. In particular, attainment of the protection objectives must be demonstrated. Experimental substantiation required for the tests in connection with dangerous goods regulations must be appended to the report.

#### Package designs subject to mandatory inspection/testing

After a successful design verification, the designer must issue a certificate of compliance whose content may be structured according to sub-section 6.4.23.14 ADR/RID. In particular, the packaging and the permitted radioactive content must be described.

#### Package designs subject to mandatory approval

In case of extensive, complex or costly testing of packaging subject to mandatory approval, the planned verification concept must be submitted to the competent authority in advance. Monitoring of manufacture as per sections 7.4.1 and 7.4.3 of this guideline must be ensured for the test samples to be used for experimental verification.

After a successful design test, the designer must apply for official approval from the responsible authority. Design documents, test and safety reports, and instructions for use and maintenance must be submitted for this purpose. The scope of the documentation to be submitted is based on the European guideline on drawing up the safety report [4] [5].

Approval must be requested from the competent authority of the country in which the design or transport originates (*country of origin*). In case of a package of fissile material or of multilateral approvals, validations or approvals must also be requested from the competent authorities of those countries where the package is to be used. Where appropriate, the competent authority may issue the designer an package design approval as per sub-section 6.4.23.14 ADR/RID.

### 6.1.4 Use, maintenance and repair

The compilation and application of use and maintenance documentation for packaging should ensure that the packaging is operated exclusively in the intended manner. The instructions on use and maintenance should therefore state, either directly or by reference to relevant documents (such as the approval certificate, test instructions), appropriate stipulations on the following points if applicable:

- Permitted contents and quantities,
- Loading and unloading,
- Securing the package during transport,
- Qualifications of the personnel and units involved,
- All measures that must be implemented during various situations, e.g. loading, transshipment and unloading, transport or intermediate stops for transport-related reasons, in order to keep the packaging in the intended condition,
- Limits that must be respected,
- Work procedures and test instructions that must be applied,
- Working and testing equipment to be used,
- Maintenance and repair,
- The nature and scope of the documentation.



This serves the purpose of keeping the packaging in the intended condition and protecting the personnel and third parties.

The designer must draw up a testing plan for the periodic tests in which the following aspects are defined: qualification and responsibility of testing staff, the individual testing steps including the test instruments and test instructions to be used and applied, and the periodicity, nature and scope of the documentation.

It should be noted in this context that packaging must be tested on a periodic (recurrent) basis for the purpose of ascertaining that the specified characteristics have not changed since the last test as a result of use, and that they are also likely to be maintained until the next periodic test is due. Testing frequencies must be defined, taking account of the time-dependent nature of safety-related material and component characteristics and in accordance with the type and frequency of use, i.e. all relevant loading and ageing effects must be considered. If the use of packaging is also to be guaranteed after an incident or accident, separate repair or maintenance measures must be presented.

## **6.2 Documents and reference material**

The design results in the following documents and reference materials:

- Design documents, such as
  - Drawings
  - Parts lists, lists of components
  - (Order) specifications, component specifications
- Safety or test report
- Instructions for use
- Maintenance instructions
- Certificate of conformance and competent authority approval respectively

## **6.3 Interactions**

### **6.3.1 Designer and manufacturer**

The designer shall hand over to the manufacturer:

- The design documents required for manufacture

After manufacture has been completed, the manufacturer shall hand over the following to the designer:

- The packaging and
- The related manufacturing documentation

### **6.3.2 Designer and owner**

The designer shall hand the following documents and reference materials over to the owner:

- Instructions for use
- Maintenance instructions
- Copies of the certificate of conformance and competent approval respectively

as well as

- The packaging and
- The manufacturing documentation



## 6.4 Supervisory measures

It is the designer's responsibility to define appropriate supervisory measures in connection with the design of components and also to guarantee individual component parameters. The outlay on supervision should generally be based on the component classification.

The supervisory measures related to manufacture are stipulated in specifications which must then be made available to the manufacturer.

The supervisory measures related to use must be integrated into the instructions on use and maintenance and must be made available to the owner of the packaging.

The designer is obliged to qualify the manufacturer of its packaging the first time and then to carry out quality checks at regular intervals, e.g. in the form of audits or fabrication monitoring. After a lengthy interruption to production, part or all of the qualification must be repeated.

All design-related documents and records, in particular including safety or test reports, certificates of conformance and competent authority approvals, must be kept in readiness by the designer and must be submitted to the competent authority for inspection on request. This also applies to qualification and audit reports, and to the QM system and the QM plan. The authority may carry out regular or event-related inspections to monitor compliance of the processes with the provisions of dangerous goods regulations.



## **7 Duties of the manufacturer**

### **7.1 Manufacture**

#### **7.1.1 Prior to the start of manufacture (specification check)**

The manufacturer is responsible for manufacturing the packaging in accordance with the requirements specified by the designer. In particular, the manufacturer must prove compliance with all safety-related characteristics and functions of the components and component parameters and of the packaging as a whole.

Before manufacture begins, it must be ensured that all relevant manufacturing processes are adequately qualified to manufacture the packaging as per the designer's specified requirements, with all the safety-related characteristics.

Especially for series production, the manufacture of packaging should be defined in the form of quality plans (FPP) based on Annex 3, which include production steps, tests and inspections in a sequential order. These FPP define the sequence of working and testing steps with reference to:

- Specifications in the form of technical drawings, material data sheets or similar,
- Work procedures and test instructions, including set-points to be respected,
- Designations of the involved parties for the individual manufacturing steps and tests as notifications,
- Nature and scope of certification and documentation,
- Serial number(s) of packaging whose manufacture is documented.

Forms may be used to enter test confirmations and, at the same time, may contain indications as to the location of additional documentation such as test protocols. The FPP and the other applicable documents are drawn up by the manufacturer before manufacturing begins.

#### **7.1.2 Manufacturing procedure**

Manufacturing is carried out with the use of manufacturing documents as specifications. In particular, the tests and inspections specified in the FPP must be carried out, and their results must be documented in test reports, certificates, test protocols and any deviation reports that may be required.

#### **7.1.3 End of manufacture**

The requirement for the commissioning of a packaging or packaging series is the successful completion of an acceptance test by the manufacturer. The acceptance test basically comprises the inspection of the manufacturing documentation. Provision may also need to be made for final inspections. The acceptance test must be an established component of the relevant FPP.

The result of the acceptance test for each packaging must be confirmed in the form of an acceptance certificate. Batch-by-batch certification is also permitted for packaging series. This certification confirms that the relevant packaging conforms to the specified design.

Following the positive conclusion of the acceptance test, the packaging must be permanently marked to indicate the period until the next periodic test. For certain types of packaging, such as one-way packaging, it may sometimes be appropriate to include an expiration date in the identification marking.

#### **7.1.4 Deviations and modifications**

If any deviations in relation to the documents drawn up prior to manufacture ( manufacturing documents) are identified during the manufacturing process, the manufacturer must issue deviation reports.

Selective modifications that are planned for one or more packagings of one design prior to manufacture are documented in a modification request.





Deviation reports and modification requests are referred to jointly as "deviation reports" (the generic term). A deviation report should include at least the following points:

- Designation of the packaging concerned,
- Serial number(s) of the packaging,
- Component concerned,
- Safety classification,
- Description of the deviation/modification,
- Cause of the deviation/reasons for the modification,
- Proposed measure(s) (e.g. repair, replacement, reworking), stating specifications and supervisory measures where applicable,
- Safety assessment by the designer, if applicable,
- Any corrective measures that may be required to prevent a recurrence,
- Name of the manufacturer,
- Name of the designer responsible for supervision, if applicable,
- Name of the authority responsible for supervision, if applicable,
- Relevant signatures.

The safety classification of a deviation/modification should be implemented as follows:

- Class A: a deviation from/modification to the requirements specified in the safety report is present.
- Class B: the requirements stated in the safety report are met. However, there is a deviation from/modification to the specified documents regarding manufacture, use or maintenance.
- Class C: the condition as per the specification is restored by means of a repair measure.

In particular, the designer must confirm the safety classification and must carry out the safety assessment for deviations or modifications in classes A and B. In addition, a statement is required as to whether the regulations under dangerous goods regulations are still met, and whether attainment of the protection objectives is still guaranteed.

Deviation reports require release by the designer and are part of the manufacturing documentation.

The manufacturer must specify measures to prevent a recurrence. If the deviation was caused by a deficiency in the measures for quality assurance or the implementation thereof, any necessary adaptations must be made to the underlying quality documents (e.g. QM plan). Where applicable, the manufacturer must present the consequences (including remedial measures) to the designer. The designer may specify more extensive measures and additional audits.

The manufacturer must also examine whether the deviations also extend to packaging that has already been manufactured and delivered. In this case, the manufacturer must inform the designer. The designer forwards this information to the owner concerned. Any remedial measures must be defined and their implementation must be coordinated between the manufacturer, the designer and the owner.

In case of modifications, it is also necessary to state which packagings in the series are affected by the modification. For a modification in Class A which is to apply permanently to the manufacture of all further packaging, the safety report must be revised by the designer and the design verification must be repeated either partially or in full.



## 7.2 Products, documents and records

The results of manufacture are:

- Packaging in compliance with the specifications,

and, especially for series manufacture, manufacturing documentation comprising:

- Specifications in the form of technical drawings, material data sheets or similar,
- Work procedures and test instructions

and the following documents and production records, as available:

- FPP
- Acceptance test certificates/material test certificates
- Test reports
- Test protocols
- Deviation reports
- Acceptance certificate

## 7.3 Interactions

See section 6.3.1 of this guideline regarding interaction between the manufacturer and the designer.

## 7.4 Supervisory measures

### 7.4.1 All packaging

It is the manufacturer's responsibility to implement appropriate supervisory measures in connection with the manufacture of packaging and its components, and also to guarantee individual component parameters. The supervisory scope is initially based on the requirements specified by the designer. The manufacturer may make provision for additional supervisory measures. Prior to manufacture, the supervisory measures must be stipulated in specifications.

The manufacturer is obliged to qualify suppliers for the first time and then to carry out quality checks at regular intervals, e.g. in the form of audits. After a lengthy interruption to production, part or all of the qualification must be repeated.

All documents and reference material of relevance to manufacture must be kept in readiness by the manufacturer and must be presented for inspection at the request of the responsible authority. This also applies to qualification and audit reports, and to the QM system and the QM plan. The authority may carry out regular or event-related audits and inspections to monitor compliance of the processes with the provisions of dangerous goods regulations.

However, manufacture should primarily be supervised on a product-related basis. Product-related monitoring is based on the manufacturing documents drawn up by the manufacturer (specifications, drawings, FPP), in which inspections, acceptance tests and checks on documentation are noted. The supervisory scope is defined by entering hold points and witness points in the relevant FPP.

In addition, certification as per SN EN 10 204 [6] may be taken into account (see Annex 2). This should be based on the component classification:



Classification	Packaging subject to mandatory approval	Packaging subject to mandatory testing/inspection
Level 1	3.2	3.1
Level 2	3.1	As per parts list
Level 3	As per parts list	As per parts list

If the ASME code is taken as the applicable set of construction regulations, the CMTR (Certified Material Test Report) must be classified as an acceptance test certificate 3.1 as per SN EN 10 204.

The results of supervisory activities, including the acceptance test certificates in particular, form part of the manufacturing documentation (on this point, also see section 7.2 of this guideline).

In case of deviations and modifications, the designer must be involved as per section 7.1.4.

Anomalies relating to the manufacture of packaging must be reported by the manufacturer to the designer. In case of anomalies in safety-relevant components or component parameters in classes 1 and 2, the manufacturer must also inform the competent authority. The designer must ensure that the information received is evaluated and taken into account as appropriate to the purpose by any other facilities which manufacture this packaging and also when drafting further designs.

#### 7.4.2 Packaging subject to mandatory testing/inspection

Supervision of the manufacture of packaging that is subject to mandatory testing/inspection is primarily the responsibility of the manufacturer. The designer has additional responsibility for supervision. He may delegate this task to an acceptance officer.

##### Prior to manufacture

The manufacturing documents drawn up by the manufacturer must be examined by the designer and must be released before manufacture commences. Moreover, the designer should enter the working steps classified by him as relevant to supervision in the FPP as hold and witness points.

Deviations from the certification suggested in the table in section 7.4.1 must be reviewed by the designer and must be released in advance.

If special proof is required in respect of manufacture or testing, it must be provided to the designer before manufacture begins, e.g. in the form of an expert material report or process test.

##### During manufacture

Inspections should be carried out by the designer according to the stipulations in the FPP. In order to carry out the inspections, the manufacturer must provide all the necessary documents and samples from production in progress. The equipment and measuring instruments for the tests must be made available to the designer, unless the tests are carried out with equipment belonging to the designer.

##### End of manufacture

Successful completion of the acceptance test must be monitored and confirmed by the designer.

#### 7.4.3 Packaging subject to mandatory approval

Supervision of the manufacture of packaging that is subject to mandatory approval is primarily the responsibility of the manufacturer. The designer and the responsible authority have additional responsibility for supervision. The designer and the responsible authority may delegate this task to acceptance officers who act independently of one another.



### Prior to manufacture

The manufacturing documents drawn up by the manufacturer must be examined by the designer and the competent authority and must be released before manufacture commences. Moreover, the designer and the competent authority should enter the working steps classified by them as relevant to supervision in the FPP as hold and witness points. The designer's entries must at least include the hold and witness points entered by the competent authority.

Deviations from the certification suggested in the table in section 7.4.1 must be reviewed by the designer and the competent authority and must be released in advance.

If special proof is required in respect of manufacture or testing, it must be provided to the designer and the competent authority before manufacture begins, e.g. in the form of expert material reports, qualification of special processes or process tests.

### During manufacture

Inspections should be carried out by the designer and the competent authority according to the stipulations in the FPP. In order to carry out the inspections, the manufacturer must provide all the necessary documents and samples from production in progress. The equipment and measuring instruments for the tests must be made available to the designer and the competent authority, unless the tests are carried out with equipment belonging to the designer or the competent authority.

In case of deviations and modifications, the designer must be involved as per section 7.1.4. In addition, the deviation report must be submitted to the competent authority after it has been released by the designer. Where appropriate, the competent authority will confirm the safety classification. For deviation reports in classes A and B, the safety assessment is also reviewed by the competent authority and the deviation report released.

If the measures to prevent recurrence in the manufacturer's deviation reports concern underlying quality documents (such as the QM plan), the measures must also be presented to the competent authority. The competent authority may order additional measures and may conduct additional audits.

If deviations or modifications also extend to packaging that has already been manufactured and delivered, the competent authority must be informed in addition to the designer. Any remedial measures must be agreed with the competent authority and their implementation must be coordinated between the manufacturer, the designer and the owner.

If a safety report is revised due to changes in class A, the safety report must be re-submitted to the competent authority. Regardless of such re-submission, the competent authority may withdraw a design approval that was issued on the basis of the previous safety report.

### End of manufacture

Successful completion of the acceptance test must be monitored and confirmed by the designer and the competent authority. The competent authority registers the accepted packagings.



## 8 Duties of the owner

### 8.1 Use

The owner of a packaging is responsible for specific aspects of the use of the package and in particular for its condition. The owner has the following principal duties:

- He must ensure that the condition of the packaging conforms to the specifications;
- He must carry out or arrange for the periodic tests and any repairs that may be needed;
- He is responsible for setting up and correctly keeping the operating manual;
- He must make the instructions for use available to the users of the packaging in a suitable language.

#### 8.1.1 Periodic (recurring) tests and inspections

Packaging must be tested on a periodic (recurrent) basis to ascertain that the specified characteristics have not changed since the last test as a result of use and that they also likely to be maintained until the next periodic test is due. Testing frequencies must be defined by the designer, taking account of the time-dependent nature of safety-related material and component characteristics and in accordance with the type and frequency of use, i.e. all relevant loading and ageing effects must be considered.

The designer must draw up a testing plan for the periodic tests in which the following aspects are defined: qualification and responsibility of testing staff, the individual testing steps including the test instruments and test instructions to be used and applied, and the periodicity, nature and scope of the documentation.

The completion of periodic testing and its results must be documented in the operating log for packaging subject to mandatory approval and in a suitable manner for packaging subject to mandatory testing. If the outcome is positive, a certificate must be issued. In addition, the packaging must be permanently marked to show the period until the next periodic test.

In the case of packaging for which the period until the next test has expired, the periodic test must be carried out before the packaging is next used.

#### 8.1.2 Repair

The purpose of repairs is to restore the condition as per the specifications by replacing and repairing components. A repair may be planned or may take place as part of preventive maintenance or in response to unexpected events during operation.

The procedure described in section 7 must be observed for the manufacture of replacement parts.

Repairs must be classified as modifications in class C, as per section 7.1.4. The corresponding procedure must be followed. Necessary manufacturing documents such as an FPP, specifications and drawings must be produced before manufacture begins and be released as per the procedure described in section 7. Attention must be paid to any supervisory measures in this context.

In case of unexpected events during operation, a safety assessment by the designer is required. The safety assessment and any measures that may be required must also be geared to potential effects on other packaging present in the enterprise.

In case of repairs, the documentation for the relevant series samples must be completed as appropriate and any necessary entries must be made in the operating log.



Provided that the relevant specialist expertise is available, the tasks to be performed by the designer as per section 7 may also be performed by the owner or assigned by the latter. This also applies to the safety assessment and any measures in connection with unexpected events during operation.

## 8.2 Products, documents and records

Except for one-way packaging, the owner shall set up an operating log for each packaging or for one packaging series. The operating log shall contain at least the following information:

- Designation of the packaging,
- Serial number of the packaging,
- Name and address of the owner,
- Reference to the certificate of conformance or competent authority approval(s), stating the validity period in each case,
- Data regarding the previous periodic test and the next periodic test,
- Entries regarding additional repairs or maintenance measures undertaken,
- Entries regarding reported defects of the packaging, with documented measures to rectify them appended where applicable,
- Information on users: name, address, data on handover and return of the packaging,
- Proof of the use of the packaging.

The owner shall ensure that the operating log is kept correctly and is up to date.

The operating log can be expanded as appropriate by adding:

- Copies of the certificate of conformance or competent authority approval(s),
- Acceptance certificate for the packaging,
- Originals or copies of maintenance certificates (e. g: certificates for successfully completed periodic tests),
- Instructions for use,
- Maintenance instructions.

## 8.3 Interactions

### 8.3.1 Designer and owner

See section 6.3.2 of this guideline regarding interaction between the owner and the designer.

### 8.3.2 Owner and user

The owner shall make the following available to the user during the period of use:

- The packaging,

together with the following documents and reference materials:

- Instructions for use, in a language that is understood by the user,
- Copies of the certificate of conformance and competent authority approval respectively,
- Copies of maintenance certificates,

After use has ended, the user shall return the packaging and the aforementioned documents to the owner.



## 8.4 Supervisory measures

### 8.4.1 All packaging

It is the owner's responsibility to make provision for appropriate supervisory measures to ascertain that the condition of the packaging conforms to the specification, that the periodic tests and any necessary maintenance and repair measures are carried out promptly, that the operating log is kept and that the instructions on use are updated as necessary.

These supervisory measures must be documented in specifications or other quality documents. All relevant documents and records, in particular including plans for the performance of periodic tests, operating logs, instructions on use and maintenance, certificates of conformance and competent authority approvals, must be kept in readiness by the owner and must be submitted to the competent authority for inspection on request. This also applies to qualification and audit reports, and to the QM system and the QM plan. The authority may carry out regular or event-related audits and inspections to monitor compliance of the processes with dangerous goods regulations.

The owner is obliged to qualify the designer of its packaging the first time and then to carry out quality checks at regular intervals, e.g. in the form of audits. After a lengthy interruption to deliveries, part or all of the qualification must be repeated.

Anomalies relating to the use of packaging must be reported by the owner to the designer. In case of anomalies in safety-relevant components or component parameters in classes 1 and 2, the owner must also inform the competent authority. The designer must ensure that the information received is evaluated and taken into account as appropriate when drafting further designs.

### 8.4.2 Packaging subject to mandatory testing/inspection

#### Periodic tests (recurring tests) and repairs

Supervision of the periodic testing and repair of packaging subject to mandatory testing/inspection is, in the first instance, the responsibility of the owner. The measures required for this purpose should essentially be based on the procedures described in sections 7.4.1 and 7.4.2.

Copies of maintenance certificates resulting from periodic tests must be made available to the user.

In case of repairs due to unexpected occurrences during operation, a safety assessment must be carried out and any measures that may be needed must be defined. If other packaging located in the enterprise is affected, the users concerned and the designer of the packaging must be informed and the necessary measures must be agreed with these involved parties. The owner must monitor implementation of the measures by the users.

### 8.4.3 Packaging subject to mandatory approval

#### Periodic tests (recurring tests) and repairs

Supervision of the periodic testing and repair of packaging subject to mandatory approval is, in the first instance, the responsibility of the owner. The measures required for this purpose should essentially be based on the procedures described in sections 7.4.1 and 7.4.3. In addition, periodic tests and repair measures should be notified to the competent authority in advance. The competent authority will then stipulate the scope of monitoring, following a safety assessment.

Copies of maintenance certificates resulting from periodic tests must be made available to the user. In addition, the maintenance certificates must be sent to the competent authority.



In case of repairs due to unexpected occurrences during operation, a safety assessment must be carried out and any measures that may be needed must be defined. If other packaging located in the enterprise is affected, the users concerned and the designer of the packaging must be informed. The competent authority must also be informed. The necessary measures must be agreed between the involved parties and with the competent authority. The owner must monitor implementation of the measures by the users and confirm this in writing to the competent authority.





## **9 Duties of the user**

### **9.1 Use**

All parties involved in transport who have or assume responsibility for a package during a transport operation should be regarded as users. According to dangerous goods regulations, these include:

- Consignors
- Carriers
- Consignees
- Loaders
- Packers
- Fillers
- Unloaders

The respective user is responsible for specific aspects of use as from transfer of the packaging or the package to him until return or forwarding thereof. The respective user is responsible for the following tasks in particular:

- He must maintain the packaging and/or the package in a condition which conforms to the specification;
- He must ensure that the package is loaded in a permitted manner as per the certificate of conformance or competent authority approval;
- He is responsible for the use of the packaging and/or package as per the instructions on use;
- He must make the necessary entries in the operating log;
- He must clean the packaging as necessary prior to forwarding.

### **9.2 Products, documents and records**

The user shall make the necessary entries in the operating manual. The operating manual is described in more detail in section 8.2.

### **9.3 Interactions**

See section 8.3.2 of this guideline regarding interaction between the user and the owner.

### **9.4 Supervisory measures**

#### **9.4.1 All packaging**

It is the user's responsibility to make provision for suitable supervisory measures in connection with the use of the packaging and the package. This applies to all activities related to such use listed in section 9.1.

The planned supervisory measures must be documented in specifications or other quality documents. All relevant documents and reference materials, in particular log books, instructions for use, maintenance certificates, certificates of conformance and competent authority approvals, must be kept in readiness by the user and must be presented to the competent authority for scrutiny in connection with inspections and, if necessary, for verification. This also applies to qualification and audit reports, and to the QM system and the QM plan. The authority may carry out regular or event-related audits and inspections to monitor compliance of the processes with dangerous goods regulations.



The user is obliged to qualify the owners of the packaging the first time and then to carry out quality checks at regular intervals, e.g. in the form of audits. After a lengthy interruption to the use of packaging, part or all of the qualification for the owners in question must be repeated.

The competent authority may carry out regular or event-related inspections of packaging and packages. The packaging or package must be made accessible to the competent authority in a suitable manner for tests in connection with the performance of inspections. The inspectors concerned must be briefed in advance on the current condition of the packaging or package by the user and must be warned of potential dangers. The ALARA (as low as reasonably achievable) principle must be observed by all involved parties. If special equipment and measuring instruments are required for the inspection and testing of packages, and in particular of packaging, prior cleaning and transfer of the package to a suitable location may be necessary. Insofar as he is able to do so, the user must assist the inspectors in this regard.

Inspections at the user's premises may include, but are not limited to, the following points:

- Condition of the packaging, including marking and labelling
- Procedures for use and handling
- Instructions on utilisation and handling that are used
- Availability and validity of the certificate of conformance
- Documents regarding maintenance, repairs and periodic tests/inspections
- Application of the QM plan
- Measures to ensure feedback of experience

Anomalies relating to the use of packaging must be reported by the user to the owner. In case of anomalies in safety-relevant components or component parameters in classes 1 and 2, the user must also inform the competent authority. The owner must forward any information received to the involved parties who are affected.



## 10 Competent authorities

The competent authorities within the meaning of this guideline are:

- FOPH for the medical and research sectors;
- Suva for the industrial sector; and
- ENSI for the nuclear installations sector.

ENSI is the competent authority for package design approvals and validations of packages and for shipment approvals in compliance with dangerous goods regulations.

The aforementioned authorities maintain a regular exchange of findings from inspections and audits and reports/notifications. This applies particularly to designers, manufacturers, owners and users who operate in several of the areas mentioned.

Contact details for the competent authorities:

Federal Office of Public Health FOPH  
Radiation Protection Department  
Schwarzenburgstrasse 165  
3003 Bern  
Email: [istr@bag.admin.ch](mailto:istr@bag.admin.ch)  
Telephone: 058 462 96 14  
[www.bag.admin.ch](http://www.bag.admin.ch)

Suva  
Rösslimattstrasse 39  
6002 Lucerne  
Email: [physik@suva.ch](mailto:physik@suva.ch)  
Telephone: 041 419 51 11  
[www.suva.ch](http://www.suva.ch)

Swiss Federal Nuclear Safety Inspectorate ENSI  
Industriestrasse 19  
5200 Brugg  
Email: [transport@ensi.ch](mailto:transport@ensi.ch)  
Telephone: 056 460 84 00  
[www.ensi.ch](http://www.ensi.ch)



## **11 Additional stipulations and information**

### **11.1 Use of packaging for interim storage**

If packaging is used for interim storage, additional regulations [7] and any conditions/requirements arising from the relevant operating licence of the interim storage facility must be observed. Interim storage must be differentiated from in-transit storage due to transport-related reasons which is part of transport according to ADR/RID 1.7.1.3.

### **11.2 Other stipulations regarding quality assurance**

If quality assurance and monitoring measures are stipulated with binding legal force within the scope of other requirements, the responsible authority may recognise such measures as substitutes.

If package designs have already received approval under dangerous goods regulations from another country, the competent Swiss authority may request proof of equivalent quality assurance and monitoring measures, insofar as its competence is affected. Provision may need to be made for compensatory measures.

### **11.3 Involved parties from other countries**

If anomalies in connection with the manufacture and use of packaging are reported to Swiss companies by involved parties from other countries, such reports must also be forwarded to the competent authority. This also applies if such findings or anomalies can be attributed to involved parties from other countries.

In all the cases cited, the competent authority decides on the further procedure.

### **11.4 Serious deficiencies in supervisory measures**

If serious deficiencies are identified in the course of carrying out supervisory measures, they must be reported immediately to the competent authority. In these cases, the competent authority may:

- Stipulate additional supervisory measures,
- Carry out audits and supervisory inspections for special reasons and
- Prohibit further manufacture and/or use until the deficiencies are rectified.



## 12 References

- [1] SN EN ISO 9000  
Quality management systems – Fundamentals and vocabulary  
December 2005 edition
- [2] SN EN ISO 9001  
Quality management systems – Requirements  
December 2008 edition
- [3] TS-G-1.4  
The Management System for the Safe Transport of Radioactive Material  
International Atomic Energy Agency (IAEA), Vienna, 2008
- [4] European Association of Competent Authorities (EACA)  
Technical Guide: Package Design Safety Reports for the Transport of Radioactive Material  
European PDSR Guide, Issue 2, September 2012
- [5] Federal Office for Radiation Protection (BfS)  
Technischer Leitfaden: Sicherheitsbericht für Bauarten von Versandstücken zur Beförderung  
radioaktiver Stoffe  
German translation of the European PDSR Guide, Issue 2, September 2012
- [6] SN EN 10 204  
Metallic products – Types of inspection documents  
December 2004 edition
- [7] Guideline ENSI-G05  
Transport and Storage Casks for Interim Storage  
April 2008 edition



## Annex 1: Sub-section 1.7.3 of the ADR/RID

### 1.7.3 Management system

1.7.3.1 A management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of ADR/RID, as identified in 1.7.1.3, to ensure compliance with the relevant provisions of ADR/RID. Certification that the design specification has been fully implemented shall be available to the competent authority. The manufacturer, consignor or user shall be prepared:

- a) To provide facilities for inspection during manufacture and use; and
- b) To demonstrate compliance with ADR/RID to the competent authority.

Where competent authority approval is required, such approval shall take into account and be contingent upon the adequacy of the management system.

## Annex 2: Test certificates as per SN EN 10 204

No.	Type of test certificate	Content of certificate	Confirmation of certification by
2.1	Compliance certificate	Confirmation of compliance with the order	Manufacturer
2.2	Factory certificate	Confirmation of compliance with the order, stating the results of non-specific testing	Manufacturer
3.1	Acceptance test certificate 3.1	Confirmation of compliance with the order, stating the results of specific testing	The manufacturer's acceptance officer who is independent of the production department
3.2	Acceptance test certificate 3.2	Confirmation of compliance with the order, stating the results of specific testing	The manufacturer's acceptance officer who is independent of the production department and the acceptance officer appointed by the party placing the order or the acceptance officer mentioned in the official regulations

**Annex 3: Example of a production and sequential test and inspection plan (FPP)**

Manufacturer		Designation of packaging:				Drawing number:		Order number – manufacturer:		Explanations: M = manufacturer C = customer A = competent authority Entries: H = hold point W = witness point		
		Serial no.:				Material:		Order number – customer:				
		Component:										
Con-secu-tive no.	Manufacturing or testing step	Applicable documents	Inspection by			Certification as per SN EN 10 204	Written proof required	Confirmations			Comments	Protocol no.
			M	C	A			M	C	A		
Documentation check comments								<b>Production and sequential test and inspection plan (FPP)</b>				
Manufacturer M				Release C		Confirmation A						
Revision	Date	Created	Checked									
Documentation review confirmations								FPP no.:				Page...
M				C		A						of ...

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