Assessment of Quality Assurance Measures for Radioactive Material Transport Packages not Requiring Competent Authority Design Approval

Steffen Komann

Federal Institute for Materials Research and Testing (BAM)
Berlin, Germany

ISSPA - International Source Suppliers and Producers Association

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1. Introduction

2. Regulations for Radioactive Materials Transport

3. Approval of Quality Assurance Measures

4. Obligations \((Manufacturer, Consignor, User)\)

5. Competent Authority Approach

6. Conclusions
Introduction

- **packages requiring a competent authority package design approval**
  (i.e. Type B packages for spent fuel elements or high level radioactive waste)

- **packages not requiring a competent authority package design approval**

  - *Excepted Packages*
    (i.e. for clinical reagents)

  - *Industrial Packages of Type IP-1, IP-2 or IP-3*
    (i.e. containers and barrels for low level radioactive waste)

  - *Type A packages*
    (i.e. for pharmaceutical products)

  require a competent authority approval for the management system
  (except for Excepted packages and Type IP-1 packages)
Introduction

Packages not requiring competent authority approval

(Picture: Maschinen-Meyer GmbH)
(Picture: Gesellschaft für Nuklear-Service mbH)
(Picture: Eisenwerk Bassum mbH)
(Picture: Eisenwerk Bassum mbH)
(Picture: Eisenwerk Bassum mbH)
(Picture: Eckert & Ziegler Nuclitec GmbH)
Introduction

**Manufacturer of the packaging**
- design and manufacture by using a competent authority approved management system

**User of the packaging**
- needs documents for a safe operation of the packaging and for its maintenance and periodic inspections

Different obligations according to IAEA-regulations

- documents must be provided by the manufacturer

Interface problems
§ 306 „Management System“ (IAEA No. SSR-6)

A Management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities in the scope of the Regulations, as identified in para. 106, to ensure compliance with the relevant provisions of these Regulations. Certification that the design specification has been fully implemented shall be available to the competent authority.

Quality assurance programme for design, manufacture, testing, documentation, use, maintenance and inspection

The Transport Regulations do not prescribe detailed quality assurance programmes because of the wide diversity of operational needs and the somewhat different requirements of the competent authorities of each Member State.
Regulations

Package Types

- Excepted Packages
- Industrial Package Type IP-1
  - Industrial Package Type IP-2
  - Industrial Package Type IP-3
  - Type A Packages
- Type B(U) Packages
- Type B(M) Packages
- Type C Packages

not requiring Competent Authority Design Approval
require a competent authority approval for the management system
IAEA-Requirements for Type IP-2:

A package to be qualified as Type IP-2 shall be designed to meet the requirements for Type IP-1... and, in addition, if it were subjected to the tests specified in paras 722 and 723 it would prevent:

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

Package Design Safety Assessment

Compliance with the Regulations → Certificate of Compliance

Responsibility of the Producer
Approval of Quality Assurance Measures

Problem:

The Transport Regulations do not prescribe detailed quality assurance programmes because of the wide diversity of operational needs and the somewhat different requirements of the competent authorities of each Member State.

National documents

German Technical Guideline (TRV 006)

- Requirements for quality assurance measures and inspections

Dangerous Goods Procedural Rules (BAM-GGR)

- Details and comments of the requirements for quality assurance measures and inspections
- Status: draft version
Obligations

Manufacturer obligations

§ 306 „Management System“ (IAEA No. SSR-6)

- Package Design Safety Assessment
  - Certificate of Compliance
- Quality Assurance Programme
  - Competent authority approved

- **Design** (package design safety report, certificate of compliance)
- **Manufacture** (fabrication and test sequence plan)
- **Testing** (experts certificate of confirmation)
- **Use, maintenance and inspection** (use and maintenance documents)
- **Documentation**
<table>
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<th>Management system</th>
<th>Quality assurance program</th>
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<td>System-related measures</td>
<td>Design-related measures</td>
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<td>- Organization of operating processes</td>
<td>- External production control</td>
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<td>- Competence/Responsibilities</td>
<td>- Design and development, radioactive content</td>
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<td>- Technological requirements</td>
<td>- Sourcing of materials/components, package</td>
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<td>- Organization, Qualification, internal audits</td>
<td>manufacturing</td>
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<td>- Cooperation of development, manufacture, quality control and operation of products (e.g. feedback, maintenance)</td>
<td>- Quality control, deviation control, signing off documents, contents of documents</td>
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<td>- Cooperation with authorities and experts</td>
<td>- Experts certificate of confirmation</td>
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<td>- Use and maintenance documents, periodic inspections</td>
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<td>- List of documents for handover to the user</td>
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<td>- Producers certificate of design compliance</td>
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<td>with the regulations</td>
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User/Consignor obligations

§ 801 IAEA No. SSR-6

For package designs where it is not required that a competent authority issue a certificate of approval, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements.

- Consignor/user needs documents for a safe operation of the packaging and for its maintenance and periodic inspections
- Documentation of the design, manufacture and testing
- Documents must be provided by the manufacturer

Interface problems
Competent Authority Approach

Competent authority approach

- Approval of the management system and assess the quality assurance program for a specific package design provided by the producer.

- Supervise the manufacturing process in terms of compliance of quality assurance measures with the requirements according to the quality assurance program.

- An audit will be performed by the authority as part of the approval process of the management system.

> Verify whether quality assurance measures defined in the quality assurance program are suitable for use in the manufacture process.

Acceptance certificate of the management system
Conclusions

1. **Management system** shall be established and implemented for all activities (design, manufacture, testing, documentation, use, maintenance, inspection)

2. **Competent authority** of the country of origin of the packaging is responsible for **approval** of this management system

3. **Consignor** must be able to show the compliance of the package design with all the applicable requirements

4. **Interface problems** manufacturer – consignor / user

5. **Majority** of transports of radioactive materials in such packages

6. **Manufacturer and users** responsibility for technical safety