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

Steffen Komann, Carsten Gröke, Bernhard Droste
BAM Federal Institute for Materials Research and Testing, Berlin, Germany

Legal Basis

IAEA - Regulations SSR-6 §306 „Management System"
ADR/RID 1.7.3 „Quality Assurance”
Competent Authority in Germany: BAM

Manufacturer’s Duties
- competent authority approved management system based on national and international standards

User/Consignor’s Duties
- demonstrate compliance with the regulations

Possibility of Penalty

Requirements/Obligations

Packaging Manufacturer

TRV006 „Technische Richtlinie über Maßnahmen zur Qualitätssicherung (QS) und -überwachung (QÜ) für Verpackungen zur Beförderung radioaktiver Stoffe“ (German Guideline)

• Design-related quality assurance measures
design, manufacture, testing, documentation, use, maintenance and inspection
  - Design/Development: package design safety assessment, safety report
  - Manufacture: fabrication and test sequence plan
  - Testing: certificate of compliance with the package design safety assessment
  - Documentation: user documentation (certificates of compliance with the regulations and with the safety assessment report, instructions for use and maintenance, acceptance certificate of the competent authority for the management system)
  - Operation: in accordance with instructions for use and maintenance

• System-related quality assurance measures

Manufacturer’s Management System (certified)

Acceptance Certificate

External Controller

Quality Assured Manufacturing

Steps:
1. Manufacturer has to provide a packaging design related management system
2. Submit management system at BAM (application)
3. Assessment by an external expert
4. Monitoring contract
5. BAM issue the acceptance certificate
6. Acceptance Certificate to Manufacturer
7. Manufacturing according to approved management system
8. External supervision of manufacturing
9. Submit external audit report to BAM

Assessment of Quality Assurance Measures in Germany