

Improvements & Challenges Associated with Non-SNF Type B Submissions

**Presented by Michael Fuller
at USNRC Meeting November 2014**

Background

QSA Global, Inc. Type B package manufacturer,
support transport of

- industrial radiography sources
- other gamma emitting radioactive sources

Ten active Type B Certificates with original approvals
dating back to 1975

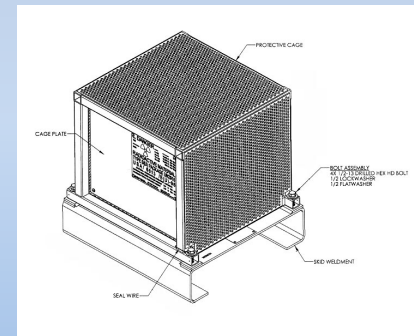
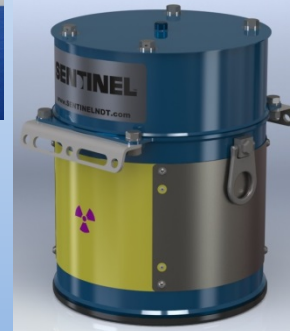
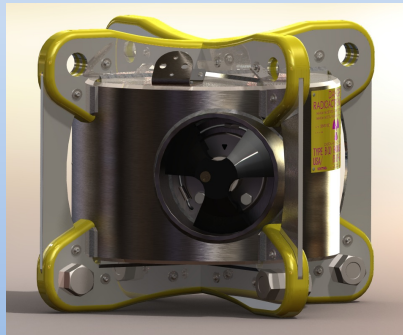
More than

- 1,500 packages a year – “Production Type B”
- 29,000 Type B(U) packages built and distributed to date

Packages

Many serve as both exposure device/source changer and shipping container.

- Small robust packages for industrial radiography (150 Ci Ir-192)
- Larger packages for industrial radiography (330 Ci Co-60)
- Source Changers (1,500 Ci Ir-192; 800 Ci Co-60)
- Bulk material containers (15,000 Ci Ir-192)



Packages

These packages:

- Are shipped daily
- Are typically shipped thousands of times over their operational lifetime
- Are used for Type B shipments spanning many years (some more than 20 years)
- Have an excellent safety record – no failures of Type B package for more than 30 years

Type B Package Submissions

Ongoing Certificate applications

- Clarifications (weld callouts, material specifications)
- Improvements (improved / alternate materials, enhanced shielding)
- New devices

Consistency & Predictability of Reviews

Historically, information requirements varied significantly from submission to submission based on reviewers involved.

Over the past few years,

- level of detail required for submissions has become more consistent
- information requests have stabilized from review team to review team.

Result:

- reduction in overall review & approval time for both new submissions and amendments.

Approval Review Improvements

The ability to know what information is necessary for review at time of initial submission means

- - - No Longer Trying to Hit a Moving Target - - -



This Improvement has:

- Minimized number of deficiency letters & requests for additional information
- Reduced the average overall review time per submission (ex: Latest, new Type B approval received in < 6 months vs the traditional 12 – 18 months)
- Improved cost budgeting for amendments & new Type B applications

Submission Review Meetings

Staff's openness to & support of interactive dialog (conference calls, meetings, etc.) during the review process has helped to:

- Reduce overall review times by allowing swift submission of needed information.
- Clarify minor issues via discussion that may not then require submission of additional information once understood.

This communication is very useful during the review process.

Draft Certificates

Issuance of draft certificates for review

- allows for the identification of errors that might otherwise require generation of a corrected copy.
- minimizes staff & applicant time in processing / tracking certificate corrections.

Additional Improvements

Consistency

- Harmonization with IAEA regulatory guidance.

Note: Endorsement to IAEA TS-R-1 2009 continues in the right direction.



Additional Improvements

When Unavoidable...

Expedited amendment to support continued container transport by package users.

- *NRC staff have worked closely with QSA to process in a timely manner
- **Greatly supports the safe use of packages.



Ongoing Challenges

Scope of Reviews

Amendment submissions run the risk of re-opening previously addressed issues that are not affected by the amendment.

Often occurs when reviewers, new to the submission, have questions about previously approved information.

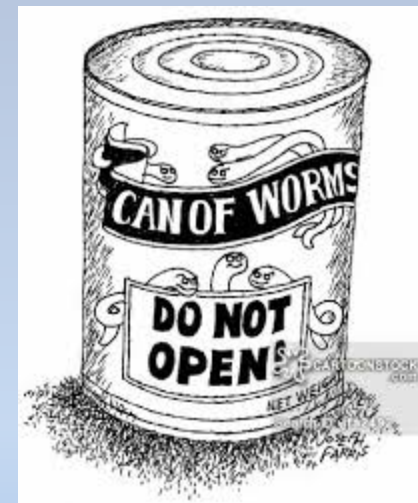


Ongoing Challenges

Result:

Applicants avoid Certificate amendments, including package improvements, because amendments risk:

- Requiring additional assessments, evaluations, testing & staff resources to re-justify previously approved information.
- Increased review time & costs per submission



Ongoing Challenges

Suggested Alternative

- Address significant safety issues¹ at time of amendment
- Note improvement items in file, address at next full renewal

Result

- Significant issues are addressed in a timely manner
- Minor amendments are not avoided

¹Significant safety issue = would require issuance of an Order to correct prior further transport

Another Suggestion

Minor Changes Without Amendment

- Internal assessment -> no impact on the Type B package integrity.
- Assessments performed under the USNRC approved Quality Assurance Program
- Integrate minor changes into certificate renewals

Examples of Minor Changes

- Revisions to Section 7 of the SAR to update Regulatory references due to regulation changes
- Modifications to components that are Not Important to Safety

Summary

Type B submission & approval process has seen numerous improvements

- Standardized information requirements
- Interactive dialog NRC <-> Licensee
- Draft certificates
- Harmonized regulations
- Expedited amendment

Continuous improvement opportunities

- Limit scope of package reviews during amendment
- Define and allow minor changes with out Certificate amendment

Questions

