Quality assurance in production and use of special form radioactive material – focal points in BAM approvals

Annette Rolle, Lothar Buhlemann
Bundesanstalt für Materialforschung und –prüfung (BAM), Berlin, Germany

Summary

BAM as the competent authority for approval of special form radioactive material attaches great importance to a detailed audit of the required quality assurance programs for design, manufacture, testing, documentation, use, maintenance and inspection. Applicants have to submit, together with application documentation information on general arrangements for quality assurance, as well as on quality assurance in production and in operation. Fields where BAM has often found deficiencies are leak test methods, weld seam quality and the safety level after use.

Introduction

Special form radioactive material is defined in No.TS-R-1 (ST1-Revised) of the IAEA Regulations [1] as either an indispersible solid radioactive material or a sealed capsule containing radioactive material. Special form radioactive material design must be able to withstand severe mechanical and thermal tests analogues to tests applied to Type B(U) packages without undue loss or dispersal of radioactive material. As a consequence the predicted hazards from inhalation, ingestion of or contamination by radioactive material after a severe accident is minimized even through the packaging may be destroyed.

This concept permits the transport of greater activity (i.e. up to A_1 instead of A_2) in a Type A package. It is essential to ensure the required level of safety for every source at any time of its working life.

To allow for this, as a result of the last revision process of the IAEA Regulation in para 310 of the requirements No. TS-R-1 (ST-1, Revised) also for special form radioactive material a quality assurance program acceptable to the competent authority is required for design, manufacture, testing, documentation, use, maintenance and inspection.

Competent authorities are required by the IAEA regulations to include a specification of the applicable quality assurance program in the certificate.

What is checked by BAM?

BAM checks the correct approach to all activities effecting the quality of special form radioactive material. Applicants have to submit a quality assurance programme including the most important measures:

General measures for quality assurance

- qualification of manufacturer and component suppliers
- structure of organization and arrangement of responsibilities
- general arrangement of documentation
- measures for inspection and marking of incoming components

Quality assurance in production

- complience of design and terms of use
- requirements for certification and inspection of safety relevant materials
- working and test instructions for all important steps of production
- methods, criteria and basic norms for leak and contamination tests
- requirements for supervision of measurement and test equipment
- requirements for qualification of staff

Quality assurance in operation

- instructions for use and maintenance
- allowable conditions of use, limited working life (as a special form material)
- necessary arrangements before transport
- arrangements for getting feedback about longterm design properties

Firstly, we assess the general arrangements for quality assurance as normally contained in the manufacturer's quality management handbook. If the quality management system is certified according to the relevant ISO-Standard, we have a good basis for our assessment. Important for us is the assessment of product specific quality assurance measures for production and use.

Common problems

Fields which are very important for the safety level of special form radioactive material and where BAM has often found deficiencies are leaktest methods, weld seam quality and the safety level after use.

Leak test methods

A volumetric leaktest is only applicable if there is a minimum void within the capsule (given in Table 1).

Leak test method	Minimum void in capsule [mm³]
Vacuum bubble	
- glycol or isopropyl alcohol	10
- water	40
- Pressurized bubble with isopropyl alcohol	10
Liquid nitrogen bubble	2
Helium pressurization	10

Table 1: Necessary minimum void in capsule for different volumetric leak test methods

Values in Table 1 are based mainly on a report of a commission of the European Communities from 1982 [2]. If a capsule has a void smaller than the values in Table 1, the applicant has to demonstrate the applicability of the test by calculation and/or experiments. Especially in the field of medicine, sources become smaller and smaller and needs for application of volumetric leaktest methods on sources with very small void increase. To upgrade its expert knowledge, BAM plans a research project about the applicability of volumetric leakage test methods on very small sealed sources.

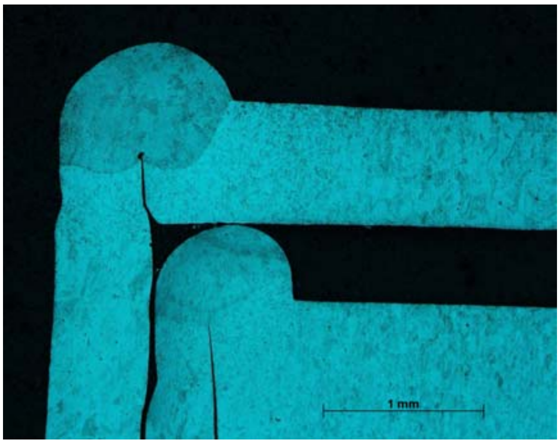
Sometimes a manufacturer intends to carry out a wet cleaning or immersion test before the bubble test. This may be a mistake. Liquid penetrating through a potential leak during this wet treatment can prevent bubble generation in the following bubble test. A potential leak will be unobservable, especially if the capsule is small and has a small void.

In case of double encapsulated sources, an immersion test for the outer capsule is not applicable if the inner capsule has already been leak tested and is free of contamination as there is no potential release.

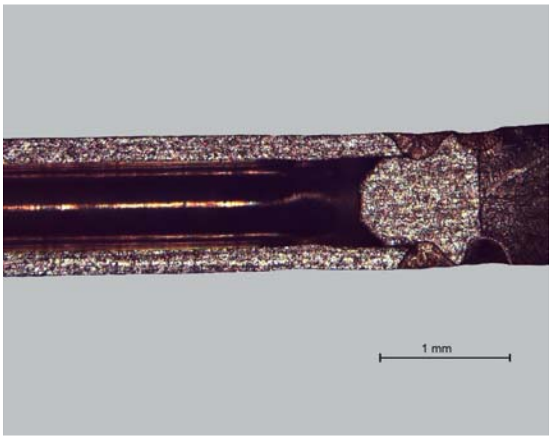
After an immersion test it is important to pay attention to sampling and measurement techniques in measuring the activity.
Sometimes – especially when only small parts of the immersion liquid are measured – manufactures disregard the detection limit which must not be higher than the predetermined limit.
Furthermore, in the case of the evaporiation of the immersion liquid, it is important to ensure that adherences inside the container do not falsify the result of the measure.
If the radioactive content is simulated, reduced, or there is a higher number of sources in one immersion test, it is important to use an adequate multiplier.

All these tips seem to be understood but, after exhaustively checking work and test instructions, BAM often finds small mistakes.
As a rule it is not satisfactory if the applicant only names the kind of test method and the basic standard in a short test instruction.

Weld seam quality
Special form radioactive materials are mostly welded capsules. The leaktightness and mechanical properties of the capsule depend on a proper weld seam. Since a high quality weld seam is so essential, it is examined in detail by the BAM approval procedure and also for an application as a new manufacturer or an extension of an approval's validity.
BAM normally makes, in addition to a visual inspection of the weld seam on test patterns , a metallographical investigation of the grinded test patterns (Fig. 1) to check conformity with the predetermined weld seam specification. We often find slight deviations. Occasionally, we find a really clear specification of weld seam geometry with appropriated deviations neither in the drawing nor in the welding instructions. There are sometimes not even welding instructions.



a) Part of a double encapsulated
´ Co-60-source, VZ-260, AEA Technology



(b)Part of a Ir-192 source for medical use,
micro Selectron HDR , Nucletron B.V.

Fig.1 Sections through welded test samples

If the laser welding technique is used, a common but incorrect assumption is that automatic manufacturing always guarantees consistant weld seam quality. Occasionally, we also find deviations from specifications on laser welded test patterns. Reasons are often to be found in maintenance intervals for the welding equipments that are too long.

As a result of our examination, applicants often have to revise or add to their welding instructions. In our experience, the best way to guarantee the safety level of weld seams is to implement periodical destructive testing in addition to monitoring weld seams by visual inspections e.g., by video control and leaktest. These destructive test methods can be for instance a metallographical examination or tensile test.

Safety level after use

Transport regulations also include range of use, maintenance and inspections because the required safety level of special form radioactive material has to be achieved in the same manner for a shipment after use. Therefore, the range of operations must be included in the quality assurance programme submitted by the applicant. BAM must be satisfied about the necessary arrangements made by the applicant.

Users must be informed about permissible conditions of use, i.e. the limits for mechanical, thermal and corrosive loading. In all cases BAM expects the specification of a safe life-span, i.e., the period in which the design's ability to meet the requirements for special form radioactive material is not reduced. After this safe life-span, there is no guarantee that the design still meets the requirements for special form radioactive material in paras 602 to 604 of the IAEA Regulations. Consequently, a shipment as special form material is not allowed after this time.

Safe life – span depends on

- design (material, wall thickness, single or double encapsulation, thin windows etc.),
- conditions of use (mechanical loads, corrosive atmosphere, temperature) and
- content (pressure build up by helium resulting from alpha emitting isotopes).

For most special form designs containing a radionuclide with a long half-life - typically, stainless steel encapsulation – the safe life-span permitted is about 10 to 15 years and also considers unexpected and unforeseeable conditions during use. This period is mostly in accordance with the period of use depending on the half life of the isotope. In other cases, a safe life-span can be limited by a fixed number of load alternations. An example is medical sources for afterloading-therapy, where a fixed number of applications before ending the safe life-span are allowed.

If an encapsulated source contains an alpha emitting isotope (for instance ^{241}Am), it is essential to quantify the pressure increase and limit this up to a value where an influence on the mechanical strength is negligible. Applicants mostly present the necessary evidence as a calculation and report on the pressure test.

Users must receive detailed instructions for use together with information about safe life-spans, guidelines for periodical inspections or other maintenance measures – if necessary – and instructions for pre-shipment activities like visual and leakage tests.

From our point of view, the approval should include a notice about safe life-spans as important information for users and competent authorities, which are responsible for supervision.

Conclusion

It is essential for the safety of transport of special form radioactive material to ensure the required level of safety – for every source at any time. Therefore, the BAM as the competent authority for approval of special form radioactive material attaches great importance to a detailed audit of quality assurance program for design, manufacture, testing, documentation, use, maintenance and inspection. In the experience of BAM, common problems are found in the fields of leakage rests, weld seam quality and safety level after use.

With its detailed audit, BAM contributes to guaranteeing the required safety level of special form radioactive materials.

References

[1] IAEA Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), Safety Standards Series No. TS-R-1 (ST-1, Revised), Vienna, 2000

[2] Aston, Dr., Bodimeade, A.H., Hall, E.6., Taylor, C.B.G., The specification and Testing of The specification and Testing of Radioactive Sources Designed as ‘Special Form’ unter the IAEA Transport Regulations, Rep. EUR 8053, CEC, Luxemburg (1982)