Bundesanstalt für Materialforschung und -prüfung

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BAM-Gefahrgutregeln (BAM-GGR)
BAM-GGR 017

Guideline for testing and approval of special form radioactive material

Revision 0

Contents

1 Objective

The Bundesanstalt für Materialforschung und -prüfung (BAM) is the competent authority for the testing and approval of radioactive materials in special form in Germany in compliance with § 8 paragraph 2 GGVSEB /1/. The standard is intended to give an overview of the basis for carrying out the type test for special form radioactive material as well as the approval procedure for these materials. The standard explains the specifications contained in the statutory regulations. The summary of the requirements for the design, manufacture and operation of types capable of approval is intended to simplify, for the applicant, the information about the content and scope of evidence and the documents to be submitted during the approval procedure.

2 Regulations and requirements

The traffic regulations for the testing and approval of radioactive materials in special form are based on the recommendations of the IAEA /2/. These recommendations are implemented in the following national and international regulations for the various different modes of transport:

Road, rail and inland waterway transport: GGVSEB /1/, ADR /4/, RID/5/, ADN/6/

Maritime transport: GGVSee /7/, IMDG Code /8/

Air transport: LuftVZO /9/, ICAO TI /10/

In /2/, the IAEA definition is as follows: "A special form radioactive material is either

- a non-dispersible solid radioactive material or
- a sealed capsule containing radioactive material."

The transport regulations /4/5/6/8/10/ lay down the design requirements for this "special form" appropriate for the stresses encountered in accident situations. Their fulfilment must be demonstrated by a type test. In the case of transport, the hazard potential of special form radioactive material is significantly lower than that of unsealed radioactive material capable of spreading. Unsealed radioactive material capable of spreading can enter the food chain, leading to long-term exposure from storage in the organ system, whereas special form radioactive material only causes danger through temporary external radiation. The transport regulations therefore stipulate transport facilitating for radioactive material which have been approved as special form radioactive material. Approved special form radioactive material with larger total activity of A_1 may be transported in Type A transport packages - a package category deemed as not accident safe. Radioactive material without this approval may only be transported in Type A transport packages up to a maximum activity of A_2. A_1 and A_2 are nuclide specific activity limits named in the above traffic regulations. Facilitations may also apply in individual cases for handling sealed radioactive material if an approval exists for the design as a special form radioactive material (see e.g. Richtlinie über Dichtheitsprüfungen an umschlossenen radioaktiven Stoffen /3/).

The design of a special form radioactive material shall meet the following requirements:
One dimension of the design shall be at least 5 mm /2, § 602/. This ensures that the material can be found and salvaged after an accident or loss.

If the special form radioactive material is a sealed capsule containing radioactive material, this shall be manufactured in such a way that it can only be opened by destroying it /2, § 604/. This should prevent easy access to the radioactive contents. In general, this requirement is only met by capsules of welded construction. Designs with a screwed lid or plug are not permitted /12, § 604.2/. If the radioactive material is enclosed several times, it must not be possible to open at least the outer enclosure which is part of the approved design without destruction.

The design shall undergo percussion, impact, bending and heat tests without breaking, shattering, dispersing, melting or leaking /2, § 603/. The test procedures are described in detail in Section 5.

After each test, the design shall be proven to be leak tight. After the leaching test, the activity in the water must not exceed a threshold of 2 kBq (see Section 3.6.1). Volumetric leakage tests according to ISO 9978/11/ can be used as an alternative. In this case, the leak-tightness criterion is a standard He-leakage rate of 10^{-5} Pa· m^3 ·s^{-1} for designs with a solid, non-leachable content and 10^{-7} Pa· m^3· s^{-1} for designs with a solid, leachable content, liquids or gases.

The design shall be resistant during its entire working life according to the type tests listed above /12, § 603.1/. The design must be planned, particularly in regard to the material and wall thickness of the enclosure, so that the operational mechanical and thermal stresses and other possible additional stresses such as, for example; abrasion, corrosion or continuous high temperatures during the period of its intended use do not lead to damage which could result in leakage under the conditions of the type test.

Activation of the radioactive material within the outer enclosure is only permitted if the leak-tightness requirements are still complied with. Enclosures of neutron sources may also only be activated to the extent that compliance with the leak-tightness criteria is easily met.

All special form radioactive material must be unambiguously identifiable by means of identification labels permanently attached by the manufacturer where the material's dimensions and condition allow. Where possible and appropriate, labels could also show other data such as a radiation warning label, radionuclide, activity, reference date for the activity and the manufacturer.

3 Design test

3.1 General information

Proof of compliance with the testing requirements must be obtained by prototype tests. All the tests can be carried out successively on a single test sample. A new test sample can also be used for each test. In principle, each test must be carried out on at least two samples. /2, § 704/

Proof of compliance with the testing requirements can also be provided as follows:

- by tests on test samples with simulated contents /2, § 704/ where it is ensured that the mechanical, physical and chemical properties of the simulated or, if necessary, inactive content or content only containing a radioactive tracer are as far as possible comparable with those of the radioactive material of the approved design, for example, in regard mass and thermal expansion,
- by tests on models of appropriate scale which contain all the essential characteristics of the aspect to be tested /4, paragraph 6.4.12/ where tests on types according to the original scale are to be preferred in every case /12, § 704.3/,
- by reference to previous satisfactory and sufficiently similar proof / 4, paragraph 6.4.12.1/,
- by calculation or reasonable argument when the calculation procedures are recognized as generally reliable or conservative /4, paragraph 6.4.12.1/.

After examining the documents submitted with the application, the BAM decides on the required number of test samples to be provided by the applicant.

Prior to the tests, it must be established that the test sample complies with the underlying design or test sample drawings. The mass of the sample must be determined. Deviations from the design specification, manufacturing defects and any damage such as, for example, corrosion or deformation must be recorded /5, paragraph 6.4.12.3/. In particular, welds or flanged edges must be examined with an optical instrument (if necessary) (stereo microscope or magnifying glass), and abnormalities must be recorded. The weld seam must be examined on the metallographic micrograph to make sure that it complies with the specifications of the design or test sample drawings in terms of width, depth, shape and permissible deviations. A separate test sample must be requested for this purpose.

The test samples must be clearly marked so that there can be no doubt about which test sample is being referred to. If the identification mark (e.g. engraving) on the design weakens the wall thickness, an identification mark with the same weakening effect must be put on the test sample.

The tests must be carried out under normal ambient conditions.

3.2 Percussion test

In order to determine the resistance to percussion, the test sample must be dropped from a height of 9 m onto an unyielding target /2, § 705/. The target must be a flat, horizontal surface and of such character that any increase in its resistance to displacement or deformation upon impact by the specimen does not lead to any significantly increased damage to the test sample /2, § 717 or 5, Section 6.4.14/. A target can be a steel-reinforced concrete foundation of at least 10 times the mass of the test sample /12, § 717.2/. The drop position must be chosen to inflict maximum damage on the test sample /12, § 705.1/. The percussion test is considered to have been passed if a final leakage test (see Section 3.6) proves the test sample to be leak tight.

If the special form radioactive material is encapsulated and has a mass of less than 500 g, the test sample can be subjected to an impact test according to DIN ISO 2919 /13/ instead. The criteria for impact class 4 apply to test samples with a mass less than 200 g and the criteria for impact class 5 apply to test samples with a mass of at least 200 g to 500 g. The test samples must be placed on a target so that they experience maximum damage from the impact of a steel, cylindrical body (hammer) of 2 kg mass (class 4) or 5 kg mass (class 5) dropped from a height of 1 m. The drop height is defined as the distance between the top of the test sample and the bottom of the drop weight. The steel impact plate (anvil) must be permanently fixed and must be at least 10 times the weight of the drop body (hammer). The top surface must be large enough to accommodate the entire test sample. The upper part of the drop body shall be provided with a fastening device and the lower part shall have a flat striking surface with a diameter of 25 ±1 mm and a rounded edge with a radius of curvature of 3 ±0.3 mm. The centre of gravity of the drop body must lie on the same axis as the centre of the impact surface. If the correct dropping position for maximum damage cannot be determined before the test beyond reasonable doubt, different positions can be tried out. The impact tests according to DIN ISO 2919 are considered passed if the sample is able to maintain its leak tightness demonstrated by an appropriate leakage test as in Section 3.6.

If the radioactive material is inside several enclosures, it is sufficient for there to be at least one enclosure which is still leak tight after the test.

3.3 Impact test

The test sample mustl be placed on a of lead sheet in a position where it experiences maximum damage from the impact of a mild steel bar (hammer) corresponding to the effect of a mass of 1.4 kg dropped from a height of 1 m. The bottom of the steel rod must have a flat striking surface of 25 mm diameter with a rounded edge with a curvature radius of 3 ±0.3 mm. The lead plate can be up to 25 mm thick but must lie on a smooth, solid surface and have a larger area than the test sample. The Vickers hardness of the lead should be between 3 HV and HV 4.5. The surface of the lead sheet must be undamaged before each test. / 2, § 706/

The impact test has been passed if the subsequent leakage test according to Section 3.6 shows that the test sample is leak tight.

The impact tests under class 4 or 5 according to DIN ISO 2919, which can be used as an alternative to the mechanical shock test according to section 3.2 for samples of lower masses (<500 g), lead to higher loadings and can be used to replace the test in Section 3.3.

3.4 Bending test

The bending test is only required for long, thin radioactive sources with a minimum length of 100 mm and a ratio of length to width of at least 10. The test sample mustl be clamped horizontally so that one half of its length protrudes from the clamp. The test sample must be positioned to suffer maximum damage when its free end is struck with a blow corresponding to the effect of a mass of 1.4 kg dropped from a height of 1 m. The blow must be struck with a steel bar, the diameter of the bottom surface of which is 25 mm with a rounded edge which has a curvature radius of 3 ±0.3 mm. /2 , § 707/

The bending test is considered passed if the subsequent leakage test (see Section 3.6) shows that the test sample is leak tight.

3.5 Heat test

The test sample must be heated to 800°C in air and maintained at this temperature for 10 minutes. It shall then be allowed to cool down. /2, § 708/

The heat test is considered passed if the subsequent leakage test (see Section 3.5) shows that the test sample is leak tight.

The test sample can also be subjected to a class 6 temperature test according to DIN ISO 2919:2012/13/ as an alternative. /12, § 709.4/ In this case, the test sample must be cooled down to a temperature of -40°C in air or a CO_2 atmosphere over a period of no more than 45 minutes and maintained at this temperature for 20 minutes. It should then be allowed to gradually come up to room temperature again. After this, the test sample must be heated to 800°C in air within a period of no more than 70 minutes and maintained at this temperature for 1 hour. Then the test sample must be quenched in water at a maximum temperature of 20°C within 15 seconds. The volume of the water bath must correspond to at least 20 times the volume of the sample. If running water is used, the flow rate must be at least 10 times the volume of the test sample per minute.

If inactive test samples or samples with simulated content are used where the real content would increase in temperature and cause a higher pressure build-up in the capsule, the strength of the capsule must also be verified by calculation under the conditions of the maximum internal pressure.

3.6 Leakage tests

A leakage test must be carried out immediately after each of the tests described under Sections 3.2 to 3.5.

Test samples which are used to represent or simulate a non-dispersible solid and are not enclosed must be subjected to a leaching test according to /2, § 710 and § 711/.

Test samples representing an enclosed radioactive material may be subjected to a shortened leaching test or volumetric leak test according to Section 3.6.2.

3.6.1 Leaching test

The leaching tests can only be used on samples with radioactive content.

The samples must be immersed in water at room temperature. The water must have an initial pH of 6-8 and a maximum conductivity of 1 mS/m at 20°C.

Samples without a sealed capsule representing a non-dispersible solid material must first be left in this water for seven days. The volume of water must therefore be sufficient for there to be an amount of unabsorbed and unreacted water remaining at the end of the period of 7 days which is equivalent to at least 10% of the volume of the test sample.

The water and test sample must then be heated to a temperature of 50 ±5°C and maintained at this temperature for 4 hours. After this, the activity of the water must be determined. If the activity measured exceeds the limit at this point, the test may be stopped. However, it may also be appropriate to repeat the test with the same test sample if it seems likely that the increase in activity in the water is due to accidental surface contamination. The test sample must then be stored for at least 7 days in still air at a temperature of at least 30°C and relative humidity of at least 90%. The leaching test must then be repeated but without storing the test sample for 7 days. The test sample is considered leak tight if the activity of the water does not exceed 2 kBq.

If the test samples tested have a reduced radioactive content, the results of the leaching test must be extrapolated, provided the conditions for the extrapolation are met. When using test samples with a simulated content, the substance which is intended to simulate the radioactive content must be enriched with an indicator. Using proportional dependence can no longer be justified if the solubility of the real content is significantly different from that of the indicator material. When determining the activity, it must be ensured that the measurement technique and sampling method are matched and that the detection sensitivity of the measuring equipment is taken into account, particularly when measuring partial amounts of the water. If the water has evaporated, it is essential to make sure that there are no deposits adhering to the evaporation vessel which could distort the results.

3.6.2 Volumetric leakage tests

According to /2, § 711 /, alternative volumetric leakage assessment methods according to ISO 9978/11/ can be used for leakage tests on test samples representing enclosed, tightly sealed radioactive materials provided their use has been approved by the BAM. The advantages of using volumetric leakage tests are that inactive test samples can be tested and the test times are shorter.

According to /12, § 603.3/ or /11, Section 4/, with the standard leakage rates of 10^{-5} $Pa·m^3·s^{-1}$ on non-leachable content or 10^{-7} $Pa·m^3·s^{-1}$ on any other content, the activity can generally be assumed to be equivalent to the required activity of ≤ 2 kBq. Non-leachable is defined as a rate of removal of radioactive material of less than 0.1 mg/g in at least 100 ml of still water within 4 hours at 50°C. /13/ (Note: a material which is considered inert is not automatically non-leachable. For example, the criterion for non-leachable was not achieved in experiments with encapsulated Ir-192 pellets./14/)

Whether the test method can be used or not depends on the size of the sample, the available free volume in the capsule, the detection limits of the method used and the physical properties of the content (leachability). The specific experimental conditions can influence the detection limits and must be taken into consideration when choosing the test methods and evaluating the test results. /12, § 603.2/

The table below shows the detection limits for the most common test methods and the minimum free volume necessary in the capsule to be tested based on /12, § 603.4/:

Test method	Detection limit [Pa· m^3· s^{-1}]	Minimum necessary free volume in the capsule [mm^3]
Vacuum bubble test		
- In glycol, isopropanol or alcohol	10^{-6} *)	10
- In water	10^{-5} *)	40
Bubble test after pressurisation	10^{-6} *)	10
Bubble test in liquid nitrogen	10^{-8} *)	2
Helium mass spectrometer test		
- Helium test	10^{-8} to 10^{-12}	10
- Helium pressure test	10^{-8}	10

*The detection limit only applies to the case where there are individual leaks under favourable observation conditions.

Table 1: Detection limits and necessary free volume. The data are based on the results of a research project on the specification and testing of radioactive materials in special form. The results are summarised in /14/.

3.6.2 Leakage tests with helium

BAM predominantly uses helium test-gas methods for leakage tests on inactive samples after the type tests. According to Table 1, these tests require a minimum free volume of 10 mm^3. When testing very small capsules, they can be opened (e.g. sawn) and bonded to the inside of larger test samples to increase the test volume in order to test the leak tightness of the weld. It is important to make sure that the bonded area is leak tight. This is usually carried out with a stereo microscope.

After using helium test -gas methods, it is important to test the test sample for the presence of large leaks using a relatively insensitive method (e.g. bubble test) since the leak tightness of the sample could be falsified because of the premature escape of helium through large leaks. Bubble tests should not be carried out under any circumstances prior to leakage tests with helium, since small leaks can be clogged by trapped liquid and the results for the test sample falsified when using a test-gas method.

The ISO standard 9978:1992/11/ makes a distinction between leakage tests using a helium mass spectrometer and the helium pressure test.

3.6.2.1.1 Helium mass spectrometry

The gas in the free volume of the test sample must contain at least 5% He. The test sample must be introduced into a suitable vacuum chamber which is evacuated and connected to a suitable, calibrated He-mass spectrometer. The measured helium leakage rate divided by the He concentration in the free volume of the test sample corresponds sufficiently accurately to the desired standard leakage rate.

The test sample is considered leak tight if the standard leakage rate determined does not exceed a value of 10^{-5} Pa·m^3·s^{-1} for non-leachable content or 10^{-7} Pa·m^3·s^{-1} for leachable, liquid or gaseous content.

3.6.2.1.2 Helium bombing test

The test sample is placed in a pressure chamber. The test sample must be subjected to helium at an appropriate pressure for a suitable length of time. After the pressure has been released and the surface cleaned using compressed air, for example, the test sample must be tested according to the procedure described in Section 3.6.2.1 to check for escaping helium. The following then applies to the standard leakage rate on the test sample:

$$Q_R = \frac{Q_L}{p_0} p \left(1 - e^{-Q_L \frac{t}{p_0 V}}\right) e^{-Q_L \frac{T}{p_0 V}}$$

Q_R Permissible leakage rate indicator (rejection limit) in Pa·m^3·s^{-1}

Q_L Permissible leakage rate of the test object in Pa·m^3·s^{-1}

t Bombing time in s

T Waiting time between pressure storage and test in s

p Bombing pressure in Pa

p_0 Atmospheric pressure in Pa

V Internal free volume of the test object in m^3

The test sample is considered leak tight if the standard leakage rate determined does not exceed a value of 10^{-5} Pa·m^3·s^{-1} for non-leachable content or 10^{-7} Pa·m^3·s^{-1} for leachable, liquid or gaseous content.

3.6.2.2 Bubble leakage test

In general, a bubble test must only be used for testing a special form radioactive material if the radioactive content is non-leachable. The corresponding proof must be provided (see 3.6.2).

The bubble test method involves creating a pressure difference across a leak and watching for the formation of bubbles in a liquid. The minimum leakage rate detected by the method depends on the pressure difference, gas used and test liquid. The detection limits vary for the different methods between 10^{-5} and 10^{-8} Pa·m^3·s^{-1} as shown in Table 1. It is essential to make sure that the bubble formation can be observed sufficiently well. Direct visual observation is normally adopted when the surface is directly visible from a distance of up to 0.6 m at an angle of less than 30°. Adequate lighting (350-500 lux) must be provided. Indirect observation via mirrors, telescopes, endoscopes or other aids may be necessary, in which case the resolution should be comparable to that of direct observation. Special attention must be paid to the weld areas. The test object must be thoroughly cleaned since surface contamination, such as grease, rust and cinder etc., can interfere with the bubble formation. Bubbles adhering to the surface, especially on the bottom, can distort the test result. These can be removed with ultrasound, for example. A leak is usually identified by a clear stream of bubbles. When choosing the test liquid, it should be noted that for any given leak the bubble stream increases with decreasing surface tension. In liquids with increased viscosity, the buoyancy is delayed so a single bubble must be observed for a longer time. (See also DIN EN 1593 /16/)

If no bubble formation can be observed, the standard leakage rate used for the detection limit for the method is considered met.

3.6.2.2.1 Vacuum bubble test

A test liquid with the lowest possible surface tension (ethylene glycol, isopropyl alcohol, mineral oil or silicone oil, or water with a wetting agent) is initially degassed by evacuating the tank volume above the liquid for at least 1 minute in a suitable vacuum chamber. After the chamber is vented, the test sample must be placed at least 5 cm below the surface of the liquid and the container volume above the liquid evacuated to about 25 to 15 kPa. The test sample must be observed for at least 1 min to look for bubbles. If no gas bubbles appear, it can be assumed that the standard leakage rate is less than 10^{-5} $Pa \cdot m^3 \cdot s^{-1}$. The test sample (assuming the content is non-leachable) is then considered leak tight. The minimum free volume necessary for the vacuum bubble test is 5-10 mm^3 when using ethylene glycol or isopropyl alcohol or 30-40 mm^3 when using water /14/. If test samples with a smaller free volume are subjected to the vacuum bubble test, the test must be shown to be applicable for this. This can be achieved, for example, by studying the bubble formation on test samples with a leak which has been deliberately introduced.

3.6.2.2.2 Gas pressurisation bubble test

The test object must be held in a gas, preferably helium, at a pressure of at least 1 MPa for 15 minutes in a suitable pressure chamber with a volume at least twice as large as the volume of the test sample and at least five times as large as its free volume. Immediately after the pressure has been released, the test sample must be immersed in the test liquid (water, alcohol, acetone or, preferably, isopropanol) at least 5 cm below the surface. The test sample must be observed for at least 1 min to look for bubbles. If no gas bubbles appear, it can be assumed that the standard leakage rate is no greater than 10^{-5} $Pa \cdot m^3 \cdot s^{-1}$. In this case, the emitter is considered leak tight (provided the content is non-leachable). The sensitivity and detection limit of the method of 10^{-6} $Pa \cdot m^3 \cdot s^{-1}$ specified in Table 1 is considered by BAM to be achievable only under absolutely ideal laboratory conditions and is not being used by the BAM for the time being.

3.6.2.2.3 Liquid nitrogen bubble test

The test object must be immersed in liquid nitrogen for about 5 minutes. It must then be watched for bubble formation in a test liquid (preferably methanol, isopropanol or ethylene glycol) for at least 1 min. If no gas bubbles appear, it can be assumed that the standard leakage rate is no greater than 10^{-8} $Pa \cdot m^3 \cdot s^{-1}$. The test sample is then considered leak tight.

The minimum free volume required for using the test is approx. 2 mm^3 as shown in Table 1. BAM also has reports from applicants which demonstrate that this test method can be used for much smaller volumes.

4 Management system

According to /2, § 306/, quality assurance programmes based on international, national or other standards acceptable to the competent authority are required for the design, manufacture, testing, documentation, use, maintenance and inspection of special form radioactive materials. BAM evaluates the suitability of the quality assurance programmes as part of the approval. The aim of quality assurance is to ensure that every source manufactured complies with the applicable transport regulations during its entire working life. It must be possible to submit proof to BAM that the series production samples fully comply with the design specification. Both manufacturers and consignors and users must enable the competent authority to request an inspection during the manufacture or use of the emitter types. It must be possible to demonstrate to the competent authority that the manufacturing methods and materials used are in line with the approved design specifications. A distinction must be made between the general quality assurance measures, i.e. the quality management of a company, such as rules about responsibilities, general documentation control and test equipment, which should be certified in accordance with the relevant standards (ISO 9001), and the specific measures relating to the actual product being approved, such as certification requirements for safety-related materials, methods and scope of production-related tests and handling and maintenance instructions.

4.1 Design, manufacture and testing

It is necessary to check whether the design corresponds to the intended range of application. The working life must be specified. This working life is defined as the period of time in which it can be safely assumed that the source design (provided it is used as intended) fully meets the transport requirements which apply to a special form radioactive material. Key design features, such as the material, wall thickness and single or double enclosure, must take into account the working life and conditions of use (such as high or low temperatures and corrosive atmospheres).

The design documentation must be checked.

Where the material properties are relevant to safety, only materials which have a test certificate may be used. The requirements for certification must be specified. BAM does not necessarily expect an acceptance test certificate "3.1" according to DIN EN 10204 /15/. However, it must be possible to confirm compliance with special material specifications, guarantee freedom from error and rule out the possibility of mistaken identity of the material. A test report "2.2" makes sense in which the test results are presented and the manufacturer confirms that the products delivered meet the requirements of the order. The regulations concerning incoming inspections and labelling must be complied with.

The basic working and test procedures for source manufacturing must be clearly shown on a production and inspection sequence plan, for example. The method, criteria, scope and standards references must be cited for tests such as leakage, contamination and dose-rate tests. The order in which the individual test steps are carried out must be followed. A possible source of error could be, for example, carrying out a wet wipe or immersion test as a contamination test before the bubble test. Liquid could penetrate a potential leak during the wet treatment and prevent bubble formation in the leak test which follows. The leak would then remain unnoticed, particularly in small capsules of low free volume.

Evidence supporting the applicability of the leakage tests must be provided. This will include, for example, evidence of the leachability of radioactive material when using the leaching test and evidence that volumetric leakage tests can be used on source designs with a very small free volume. With double enclosed sources, the leaching test is not applicable for the outer enclosure when the inner capsule has already been tested for leak tightness and is free of contamination since, in this case, no release of activity is possible.

When evaluating the leaching tests, particular attention must be paid to the sampling method and the measurement method. Another source of error with small source designs is to neglect to use the multiplier necessary for determining the released activity when larger quantities are examined in a test.

In order for the source design to achieve the required leak tightness and mechanical strength, it is particularly important that the weld be of a high quality. The quality assurance measures during the production and testing of welds must be appropriate for ensuring that the weld is of a consistent quality. The production documents (drawings and work instructions) must contain clear specifications for the execution of the welds. The weld shape (width and depth) and permitted tolerances must be specified. Welding procedure specifications must be prepared based on the relevant national or international welding technology standards. Test instructions must be prepared for the weld inspection which includes the welding process (e.g. video monitoring), visual inspection, leak test and random metallographic or tensile tests.

When using the laser technique, it is often assumed erroneously that automated production guarantees consistent production quality. If the necessary maintenance intervals calculated are too long, this can lead to deviations from the specified weld seam quality. The welding personnel must be sufficiently qualified. If necessary, the qualifications can be established by work instructions for the training of welding machine operators.

BAM ensures that the production quality of the welds is of a high enough standard by carrying out metallographic tests on a test sample.

4.2 Operation

The tested safety level of special form radioactive materials must be maintained for transport all the time, even for transport after longer-term use /12, § 603.1/. Quality assurance measures in regard to use, maintenance and inspection are therefore a requirement in the transport regulations.
The applicant must ensure that the user is provided with detailed information regarding

- regulations for use,
- permissible useful life (see also 4.1),
- permissible limits for mechanical, thermal and corrosive stress,
- specifications for periodic inspections or other maintenance procedures and
- necessary measures before (re-) transport.

The required specification of a working life only applies to the validity of the approval as a special form radioactive material, i.e. to the preservation of the safety-related properties, when approval of the tested properties of the type has been granted. After this working life a transport of the source as a special form radioactive material is not permitted anymore.
The working life may depend on the source design (materials, wall thickness and whether it is single or double enclosed), the operating conditions and the content (e.g. pressure build-up with helium). The permissible working life recommended by the applicant is usually in good agreement with the technically feasible working life, which is dependent on the half-life of the isotope. In other cases, the permissible working life depends on the number of load cycles, as with sources used for medical applications.
If the source contains an isotope which emits alpha radiation, proof must be provided to show that the pressure increase inside the capsule due to the formation of helium will not cause damage. The applicant must provide calculated proof or test reports on pressure tests which have been carried out.

The owner of the approval is entitled to apply for an extension to the specified service life at any time based on new knowledge, experience feedback, etc.

4.3 Measures before (re-) transport

The applicant must determine any additional measures necessary before re-transport after use. These must ensure that the source has not been damaged by unexpected impacts during its working life. These are generally visual and leakage tests. The last leakage test carried out on a source with positive results should not have been carried out more than 0.5 to 1 year before re-transport. The manufacturer must inform the user of the necessary measures.

5 Approval

The design approval is granted once tests on the design have been completed with positive results: these include the design test and the management system as described in detail in the preceding chapters 3 and 4. See also Chapter 3.3 of guideline R 003 /18/ for the procedure.

5.1 Responsibility

According to /2, § 803/, the design of a special form radioactive material requires unilateral approval, i.e. approval must be granted by the competent authority in the country of origin of the source design. In Germany, according to GGVSEB /1/, the competent authority for granting this approval under the transport regulations is BAM. BAM may also grant approvals for other European manufacturers, provided the competent authorities of those countries agree. Foreign manufacturers submit applications for approvals to BAM because BAM has many years experience with testing sealed radioactive sources or the need for such approvals in the country of origin is so low that the authorities there do not want to go to the expense of providing the material and personnel required to carry out the testing and approval work.

5.2 Application

A single copy of the application for the design approval for a special form radioactive material, including all the required documentation in accordance with Section 5.3, must be submitted to BAM. BAM will confirm receipt of the application.

5.3 Documents to be submitted

The following information and documents must be submitted with the application to BAM:

- applicant,
- the manufacturer(s) (of the content of the capsule parts of the finished emitter),
- design specification,
- design designation,
- general assembly drawing with main dimensions, type of identification, indication of nuclide and activity (in the form of an appendix to the approval certificate),
- detailed drawings with material specifications, welding specification and engraving depth where necessary
- description of the capsule type (enclosure, type of weld and materials);
- description of contents (radionuclide with purity specification, activity, chemical compound of the radioactive material, physical state, useful radiation type and materials for fixing, e.g, spacers),
- applications;
- ISO classification according to ISO 2919 (with test report if necessary),
- permissible working life,
- permissible operating conditions (mechanical, chemical, thermal and corrosive),
- evidence of compliance with the testing requirements where available,
- evidence of the applicability of the leakage test methods (specification of the inner free volume or evidence on the applicability, if the volume is below the limits in Table 1),
- information on the leachability of the radioactive contents in accordance with DIN ISO 2919 and
- quality assurance programme of the applicant and manufacturer(s) for the design, manufacture, testing, documentation, use, maintenance and inspection.

If the management system of the applicant or the manufacturer(s) is certified according to DIN EN ISO 9001 /17/, BAM must be presented with the current certificate. In this case, it is not necessary to present information on the general QA rules, such as manufacturer qualification, documentation rules and responsibilities etc.

BAM expects the following information on design, manufacture and testing:

- design requirements, underlying rules and regulations,
- certification requirements, incoming inspection and labelling for safety-related materials and semi-finished products,
- work and test instructions for the key production and test procedures,
- instructions on the inspection and maintenance of production and test equipment and
- qualification of specialist personnel (e.g. training of welders).

All documents relating to user instructions in regard to operation, maintenance and inspection must be presented to BAM:

- handling and maintenance instructions,
- evidence of user's information on the permitted working life and operating conditions,
- evidence of ensuring information feedback in order to assess the service experience and
- specification of necessary measures (e.g. inspection and leakage tests) before re-transport.

5.4 Content of the approval certificate

An approval certificate must contain the following information in accordance with /2, § 834/: type of certificate, competent authority identification mark,

a) issue and an expiry date,
b) list of applicable national and international regulations, including the edition of the IAEA Regulations on the Safe Transport of Radioactive Material according to which the special form radioactive material has been approved,
c) identification of the special form radioactive material,
d) description of the special form radioactive material,
e) design specifications for the special form radioactive material which may include references to drawings,
f) specification of the radioactive contents, including information on the activities involved and the physical and chemical form,
g) specification of the applicable management system,
h) reference to information provided by the applicant relating to specific actions to be taken prior to shipment,
i) information on the identity of the applicant and
j) signature and identity of the certifying official.

An approval certificate of the BAM is organised as follows:

1. regulations,
2. applicant and holder of the approval,
3. manufacturer,
4. relevant documents of the applicant,
5. design designation, radionuclide and activity;
6. drawings,
7. description of design,
8. management system,
9. design test,
10. design approval,
11. incidental provisions;
12. notes and
13. legal advice.

The appendix of an approval certificate contains a general assembly drawing for each design which must contain all the important information on the design identification, such as the main dimensions, maximum activity, identification of the weld, material specifications and type designation. The above revision steps are also summarised in an enclosed overview.

5.5 Validity and extension

The period of validity of the approval certificate must be in accordance with /2, § 834/. BAM usually limits the period of validity to 5 years. This period can also be shortened in accordance with any foreseeable changes in legislation governing the validity. The validity of the approval certificate will be renewed upon application provided there are no reservations about an extension for reasons of safety. The application for renewal must be submitted to BAM at least 6 weeks before the expiry date.

Changes in the design, quality assurance programme, manufacturer or approval certificate holder

Any changes to the type or quality assurance programme must be approved by BAM. BAM must be notified in every case. BAM will decide whether there is a need to revise the approval before the expiry date or a need for additional or new safety certificates based on the effect of the changes on safety.

A revision of the approval certificate can be requested if there are any changes regarding the company name, address or legal status of the approval certificate holder. The legal succession must be evidenced by the presentation of an extract from the Commercial Register. The new company must appear in the approval liabilities with the same rights and obligations.

Literature references

/ 1/ Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße, mit Eisenbahnen und auf Binnengewässern (Gefahrgut-verordnung Straße, Eisenbahn und Binnenschifffahrt - GGVSEB -) vom 22. Januar 2013 (BGBl. 2013 I S. 110) / 2/ Regulations for the Safe Transport of Radioactive Material, 2012 Edition, International Atomic Energy Agency (IAEA), Specific Safety Requirements No. SSR-6, Vienna, 2012

/ 3/ Richtlinie über Dichtheitsprüfungen an umschlossenen radioaktiven Stoffen vom 4. Februar 2004, (GMBl 2004, Nr. 27, S.530 ff)

/ 4/ European Agreement of 30th September 1957 concerning the International Carriage of Dangerous Goods by Road (ADR) (Federal Law Gazette. 1969 II p 1489), last amended by the revision of Annexes A and B in the version published on 3rd June 2013 (BGBl.2013 II p 648

/ 5/ Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) - Enclosure I to Appendix B to the Agreement Concerning International Carriage by Rail of 9th May 1980 (Federal Law Gazette 1985 II p 130.) in the version published on 16th May 2008 (Federal Law Gazette 2008 II p 475) as last amended by the 18th RID Amendment Regulation of 25th May 2013 (Federal Law Gazette., 2013 II p 562)

/6/ European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) of 26th May 2000 (Federal Law Gazette. 2007 II p 1906, 1908), last amended in accordance with the 4th ADN Amendment Regulation of 3rd December 2012 (Federal Law Gazette 2012 II p 1386)

/ 7/ Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen (Gefahrgutverordnung See-GGVSee) in der Fassung der Bekanntmachung vom 16. Dezember 2011(BGBl. I 2011, S.2784, BGBl. I 2012 S.122), zuletzt geändert durch Artikel 4 der Verordnung vom 19. Dezember 2012 (BGBl. I S. 2715)

/ 8/ International Maritime Dangerous Goods Code (IMDG-Code), amended 35-10,

/ 9/ Luftverkehrs-Zulassungs-Ordnung in der Neufassung vom 10. Juli 2008 (BGBl. I S. 1229), zuletzt geändert durch das Gesetz vom 22. Februar 2011 (BGBl. 2011 I S. 317)

/10/ International Civil Aviation Organisation (ICAO), Technical Instructions for the Safe Transport of Dangerous Goods by Air, Edition 2011/2012

/11/ ISO 9978: 1992: “Radiation protection – Sealed radioactive sources - leakage test methods”

/12/ Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Standard Series No. TS-G-1.1, Rev.1, International Atomic Energy Agency (IAEA), Vienna, 2008

/13/ DIN ISO 2919:2012-08 Radiation protection - Sealed radioactive sources - General requirements and classification

/14/ D. Aston, A.H. Bodimeade, E.G. Hall, C.B.G. Taylor: "The specification and testing of radioactive sources designated as special form under the IAEA Transport Regulations", EUR 8053 EN Report, Brussels, Luxembourg 1982

/15/ DIN EN 10204: 2004 (January 2005): "Metallic products - Types of test certificates"

/16/ DIN EN 1593:1999 "Non-destructive testing - Leak testing - Bubble emission techniques"

/17/ DIN EN 9001:2008: Quality Management System Requirements (ISO 9001:2008)

/18/ Richtlinie für das Verfahren der Bauart-Zulassung von Versandstücken zur Beförderung radioaktiver Stoffe, von radioaktiven Stoffen in besonderer Form und gering dispergierbaren radioaktiven Stoffen, in der Fassung vom 17. November 2004 (VkBl. 2004 S. 594) und der Bekanntmachung des BMVBS zu Richtlinien zu den Gefahrgutvorschriften vom 01.Juli 2010 (VkBl. 2010 S. 282)