



**State Office for Nuclear Safety
Senovážné nám. 9, 110 00 Prague 1**

Prague, on 9 September 2008
Ref. no. 19481/2008
File no. SUJB/POD/17101/2008
Nuclear Installation Assessment Department

DECISION

The State Office for Nuclear Safety (SONS) as the competent administrative body pursuant to Section 3 (2) (c) of Act no. 18/1997 Sb., On Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Additions to Related Acts, as later amended, has decided as follows in the administrative proceedings initiated pursuant to Section 44 (1) of Act no. 500/2004 Sb., Rules of Administrative Procedure (hereinafter referred-to as “RAP”), on 23 July 2008 on the basis of an application filed by a participant in proceedings as defined in Section 27 (1) (a) RAP – Eckert & Ziegler Cesio s.r.o., Radiová 1, 102 27 Prague 10, Identification Number 45274584, Registration Number 108600 (hereinafter referred-to as “Participant in Proceedings”), on 21 July 2008 under file no. 024/EZC/08 in the matter of type approval of a special form radioactive material:

SONS, pursuant to Section 67 (1) of Act no. 500/2004 Sb. and Section 23 (2) of Act no. 18/1997 Sb., as later amended,

approves

Construction type **Am1.N02** as a special form radioactive material, this material, manufactured in conformity with the documentation assessed, being assigned the identification designation

CZ/1009/S-96

and, for the purposes of international identification, this type approval decision being assigned the code designation

CZ/1009/S-96 (Rev. 1).

Type Am1.N02 special form radioactive material complies with the requirements of Act no. 18/1997 Sb., as amended, as well as the relevant implementing regulations, the recommendation of the International Atomic Energy Agency titled “IAEA Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material, 2005 Edition, Safety Requirements, International Atomic Energy Agency, Vienna, 2005” and international transportation regulations that refer to the cited IAEA’s rules.

This Decision is valid until: 31 December 2013.

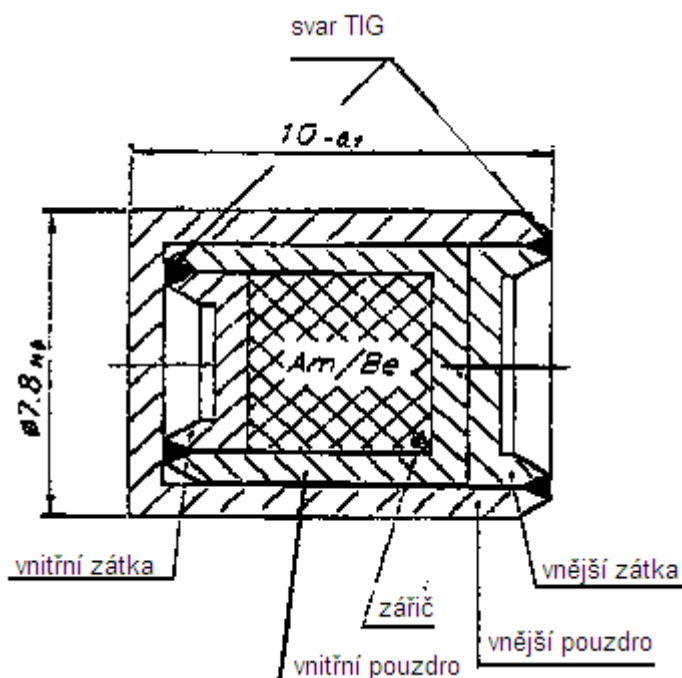
Description of the Special Form Radioactive Material:

Am1.N02 special form radioactive material is a cylinder that consists of an outer, stainless-steel case closed with a plug welded on by welding in protective atmosphere, an inner case of stainless steel, too, closed with a plug welded on by welding in protective atmosphere and a radionuclide emitter. A distance piece fixes the inner case so that the radionuclide emitter is in close contact with the outlet hole of the outer case, 0.2 mm thick.

The Applicant is the manufacturer of the Am1.N02 special form radioactive material.

Parameters:

Special Form Radioactive Material Type	Height [mm]	Diameter [mm]	Maximum Activity [GBq]	ISO Classification
Am1.N02	10	7.8	3.7	66545

Image of the Special Form Radioactive Material:

svar TIG = TIG weld, vnitřní zátka = inner plug, vnitřní pouzdro = inner case, zářič = emitter, vnější pouzdro = outer case, vnější zátka = outer plug

Labelling:

Am1.N02 special form radioactive material shall be labelled with the following data, in a clear, legible and durable manner:

- Serial number
- Identification designation CZ/1009/S-96

If it is not technically possible to place the identification designation onto the case of the special form radioactive material, it shall be replaced by the type approval decision.

Conditions for Use:

Am1.N02 special form radioactive material under identification designation CZ/1009/S-96 can be used only subject to the compliance with the following conditions:

1. Permitted radioactive content of the special form radioactive material

Am1.N02 special form radioactive material under identification designation CZ/1009/S-96 (hereinafter referred-to as “product”) with the given serial number may only contain a radionuclide emitter consisting of a fixed, burned ceramic carrier that contains ²⁴¹Am radionuclide in the form of americium oxide fixed by the burning process, with maximum activity of 3.7 GBq.

2. Conformity of the properties and parameters with the approved type

The manufacturer shall prove the conformity of the product of the given serial number with the approved type by a written Declaration of Conformity pursuant to Section 6 (2) (c) of Decree no. 317/2002 Sb., On type approval of packaging for shipment, storage and disposal of nuclear materials and radioactive substances, on type approval of ionizing radiation sources, and on shipment of nuclear materials and specified radioactive substances (on type approval and shipment).

Type-approved special form radioactive material can be put into circulation if its conformity with the approved type has been proved by an acceptance test of the special form radioactive material substantiated with a test report.

3. Quality Assurance

Each product must be manufactured in accordance with technical drawing Am1.N02 Am – Be NEUTRON SOURCE Am1.N02, 1.207.02.02-00:00 (4), BEBIG Isotopentechnik und Umweltdiagnostik GmbH, of 2 May/28 July 1995, approved procedures and the approved Quality Assurance Programme QM-Q-001, as amended. Handling, operating checks and use of the product in approved apparatuses must follow manufacturer-approved instructions. The instructions can be modified in accordance with requirements of competent bodies of the country in which the product is disposed of.

The number and term of validity of this Decision must be stated in the documentation to be handed over to the user together with the product.

The Decision of Type Approval of Am1.N02 special form radioactive material under identification designation CZ/1009/S-96 does not replace other permissions of SONS issued pursuant to Section 9 (1) of Act no. 18/1997 Sb., as amended, or permissions/licenses for activities issued by other central state administration bodies pursuant to special regulations if applicable.

Justification:

The Decision is issued under the application from the Eckert&Ziegler Cesio Company, ref. no. 024/EZC/08 of 21 July 2008, submitted to SONS pursuant to the provision of Section 23 of Act no. 18/1997 Sb., as amended, on 23 July 2008.

The application was supported with the following documents, in compliance with Section 3 of SONS's Decree no. 317/2002 Sb.:

- Data on the Applicant;
- Description of the product, its use and marketing, list of legal regulations, description of tests required;
- Quality Assurance Programme QM-Q-001 approved by SONS's Decision ref. no. 19611/2007;

- Instructions for safe handling of ionizing radiation sources QM-RP-006;
- Encapsulated Radiation Source Certificate no. 196/08 (102/08);
- Copy of the Entry in the Register of Companies;
- Affirmation pursuant to Section 13 (8) of Act no. 18/1997 Sb., as amended;
- TÜV Certificate of 9 April 2007.

The State Office for Nuclear Safety states that the assessed documentation proves that product type Am1.N02 meets the conditions of SONS's Decree no. 317/2002 Sb., On type approval of packaging for shipment, storage and disposal of nuclear materials and radioactive substances, on type approval of ionizing radiation sources, and on shipment of nuclear materials and specified radioactive substances (on type approval and shipment), for special form radioactive materials, and that's why it was decided as stated in the Statement.

The administrative fee amounting to CZK 1,000.- was paid in accordance with Item no. 107 (2b) of the Annex to Act no. 634/2004 Sb., On Administrative Fees.

Advice:

Remonstrance against this Decision can be lodged to SONS's Chairperson through SONS/SÚJB, Nuclear Installation Assessment Department, Senovážné náměstí 9, 110 00 Prague 1, within 15 days after the service hereof.

On behalf of the State Office for Nuclear Safety

Ing. Petr Brandejs
Vice-chairperson for Nuclear Safety